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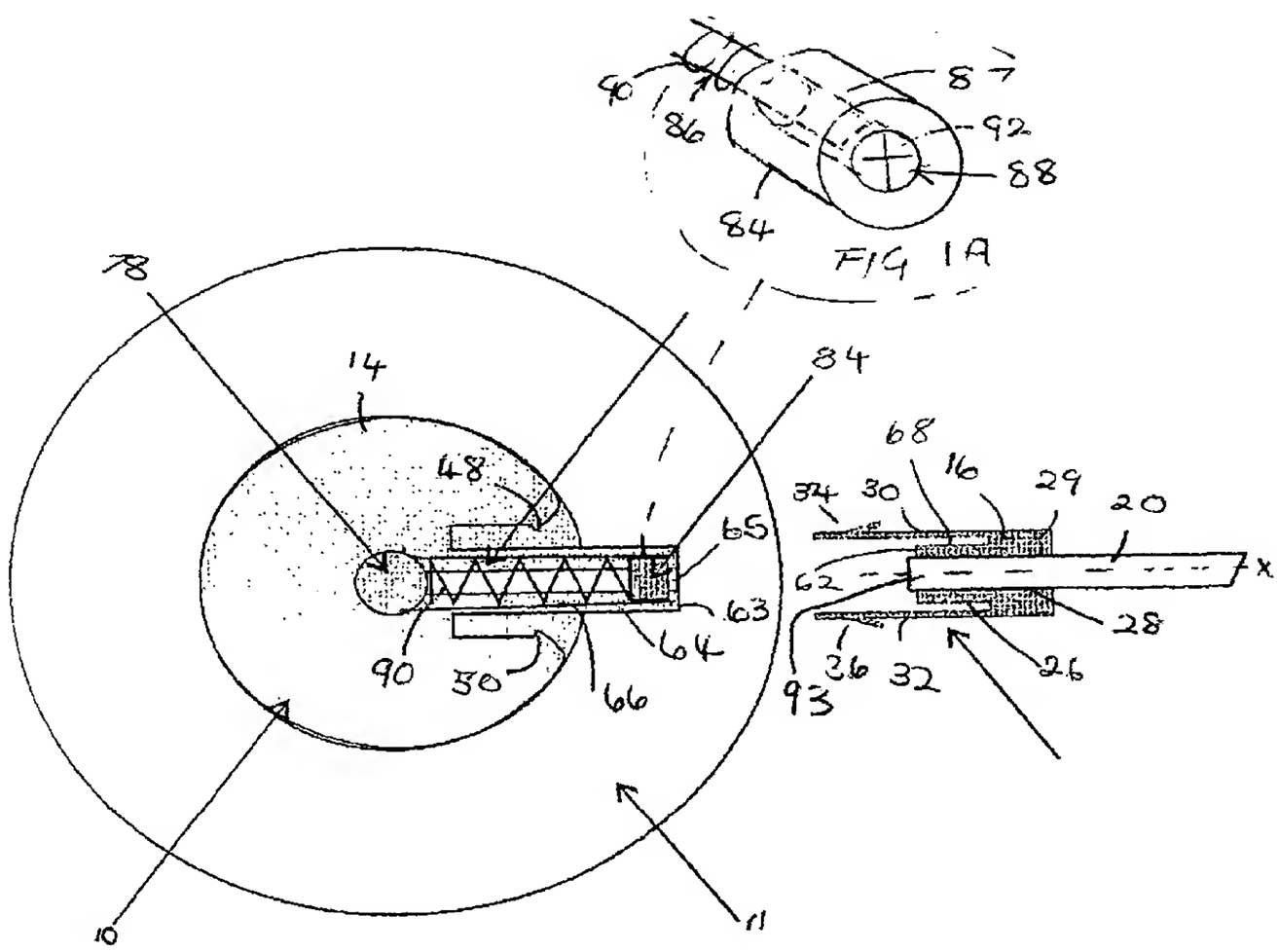
(54) Title: INFUSION SET WITH TAPE



(57) Abstract: An infusion set (1, 100, 100') is attached to the skin of a wearer by a conformable tape or path (220, 220'). The tape is of a multilayer construction, comprising a breathable layer (226, 226'), preferably formed from a silicone elastomer or hydrocolloid, and optionally a support layer (222), such as a layer of polyester. An adhesive layer (240) is provided for attaching the tape to the wearer's skin. A second adhesive layer (234), or a mechanical means (252) attaches the tape to the infusion set.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INFUSION SET WITH TAPE

Background of the Invention

[0001] The present invention relates to infusion systems for subcutaneous delivery of a medication or a therapeutic fluid into the body and more particularly to an infusion device for releasably coupling an infusion pump to a subcutaneous cannula for delivery of the medication or the therapeutic fluid.

[0002] Portable infusion devices are generally known in the art for delivering medications and other fluids, such as insulin, sugars, and painkillers, to a subcutaneous site in the body of a patient. Such devices commonly include a tubular cannula extending from a connector housing which receive the desired medication from an infusion delivery system, such as a syringe pump, or the like. The housing is typically in two parts, allowing the user to disconnect the cannula from the pump to facilitate activities, such as bathing, swimming, or the like, for which it is desirable to have the pump disconnected.

[0003] In use, the housing provides a fluid-tight connection between the housing and the tubular cannula that helps to prevent contamination of the injection site. For example, the housing may include a first portion, connected with the cannula, which includes a self-sealing penetrable septum, and a second, disconnectable portion, connected with the pump and having a hollow needle adapted to penetrate the septum. When the needle is withdrawn from the septum, a fluid-tight seal is created between

the interior of the first portion of the housing and the cannula. The septum and the needle further provide a fluid-tight seal between the cannula and a delivery tube when the medication is being delivered to the patient from the external infusion system.

[0004] Conventional infusion sets of this type tend to be unwieldy and difficult for the user to operate. There remains a need for an infusion set which is simple to operate without injury or discomfort to the user, yet which provides assurance against accidental disconnection during use.

[0005] U.S. Patent No. 5,522,803 shows an infusion set including a cannula housing, which interconnects with a needle holder. A feed line feeds a medicament to the needle holder. A connecting needle of the needle holder is introduced into a channel of the cannula housing via a septum. Guide pins, one on either side of the needle, are provided for correctly positioning the needle in the channel of the cannula housing. During advancement of the needle into the channel, the needle holder is anchored to the cannula housing by a pair of automatically engaging snap-fit tabs.

[0006] The present invention provides a new and improved infusion set and attachment system for adhering the set to a wearer's body which overcomes the above-referenced problems, and others.

Summary of the Invention

[0007] In accordance with one aspect of the present invention, an infusion set and attachment system combination is provided. The combination includes a conformable patch for attaching the infusion set to the skin of a wearer. The infusion set includes a first housing portion connected to a top layer of the patch. A second housing portion is selectively interconnectable with the first housing portion for forming a fluid passageway therebetween. The second housing portion is connected with a source of a liquid to be introduced to the wearer. A cannula is connected with the first housing portion for introducing the liquid to the wearer, the cannula passing through the patch when inserted into the wearer's skin.

[0008] In accordance with another aspect of the present invention, a method for supplying a liquid to a person is provided. The method includes attaching a patch to the skin of the user and attaching a first housing portion to the patch. A cannula of the first housing portion is inserted through the patch and into the person's skin. A second housing portion is selectively coupled with the first housing portion to form a fluid flowpath therebetween which is fluidly connected with the cannula. The liquid is fed to the first housing portion, the liquid flowing along the fluid flowpath and into the cannula.

[0009] One advantage of one embodiment of the present invention is that it is easily operated by a user.

[00010] Another advantage of one embodiment of the present invention resides in its low profile.

[00011] Another advantage of one embodiment of the present invention is that the multi-layer patch provides a support region underlying the infusion set while providing a breathable region adjacent the wearer's skin in the area of penetration of the cannula.

[00012] Another advantage of the present invention is that the infusion set is readily attached to or removed from the patch, when desired.

[00013] Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

[00014] The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

[00015] FIGURE 1 is a top plan view of a two part infusion system according to the present invention;

[00016] FIGURE 1A is an enlarged view of the stopper and tube of FIGURE 1;

[00017] FIGURE 2 is a top plan view of the two part infusion system of FIGURE 1 with the two parts connected;

[00018] FIGURE 3 is a side sectional view of the infusion system of FIGURE 1;

[00019] FIGURE 3A is an enlarged view of the cannula housing showing an O-ring for attaching the cannula housing to a cavity of the patch;

[00020] FIGURE 4 is a side sectional view of the infusion system of FIGURE 1 showing insertion of a cannula;

[00021] FIGURE 5 is a side sectional view of the infusion system of FIGURE 1 after insertion of a cannula;

[00022] FIGURE 6 is a top plan view of the two part infusion system of FIGURE 1 showing a feed tube and Luer connector;

[00023] FIGURE 7 is an exploded perspective view of an alternative embodiment of an infusion system according to the present invention;

[00024] FIGURE 8 is a side sectional view of the needle housing of FIGURE 7 with the needle removed;

[00025] FIGURE 9 is a top sectional view of the needle housing of FIGURE 7;

[00026] FIGURE 10 is a cross sectional view of the needle housing of FIGURE 7;

[00027] FIGURE 11 is a side perspective view of the cannula housing of FIGURE 7;

[00028] FIGURE 12 is a side sectional view of the infusion set of FIGURE 7 after assembly;

[00029] FIGURE 13 is a side sectional view of an insertion set according to the present invention;

[00030] FIGURE 14 is an exploded perspective view of the insertion set of FIGURE 13;

[00031] FIGURE 15 is a perspective view of the tip of the needle and catheter of FIGURE 13;

[00032] FIGURE 16 is a top plan view of the adhesive patch of FIGURE 7;

[00033] FIGURE 17 is a side sectional view of the adhesive patch of FIGURE 16 through A-A;

[00034] FIGURE 18 is a side sectional view of the adhesive patch of FIGURE 16 through B-B;

[00035] FIGURE 19 is an exploded side sectional view of the adhesive patch of FIGURE 16 through A-A;

[00036] FIGURE 20 is an exploded top view of the adhesive patch of FIGURE 16;

[00037] FIGURE 21 is a top plan view of an alternative embodiment of the adhesive patch of FIGURE 7;

[00038] FIGURE 22 is a side sectional view of the adhesive patch of FIGURE 21 through A-A;

[00039] FIGURE 23 is a side sectional view of the adhesive patch of FIGURE 21 through B-B;

[00040] FIGURE 24 is an exploded top view of the adhesive patch of FIGURE 21;

[00041] FIGURE 25 is a partially exploded perspective view of an alternative embodiment of an infusion set according to the present invention;

[00042] FIGURE 26 is a side sectional view of the infusion set of FIGURE 25;

[00043] FIGURE 27 is a top view of one embodiment of the patch with an insertion set thereon; and

[00044] FIGURE 28 is a side sectional view of the embodiment of FIGURE 27.

Detailed Description of the Preferred Embodiments

[00045] With reference to **FIGURES 1-6**, a first embodiment of an infusion set **1** includes a two-part assembly or housing **10** with a generally planar configuration when assembled. An attachment system **11** attaches the housing to a wearer's skin **S**. A soft catheter or cannula **12** extends from a first portion or cannula housing **14** of the assembly and is received through the skin **S** of the wearer of the infusion set. The cannula is formed from a soft plastic material and has a central bore **15** through which a medicament, such as insulin, or other liquid to be infused is supplied from the assembly **10** into the user's body. A second portion or connector housing **16** of the assembly **10** is configured for releasable interlocking with the cannula housing **14**. The first portion **14** of the housing **10** is designed to remain on the user's skin for extended periods, while the second portion **16** is removed at intervals for bathing or other purposes. The connector housing **16** acts as a needleless-connector and is of a thinner cross section ***d*** than the cannula housing.

[00046] The connector housing **16** is fluidly connected with a feed tube **20.** The feed tube **20** supplies the medicament to be injected from an infusion pump (not shown), or other supply source, to the connector housing **16**. The feed tube **20** is fluidly connected with the infusion pump via a Luer connection **22** or other suitable releasable connection **(FIG. 6)**. Although the system **1** is described in terms of fluid flowing downstream from the feed tube **20** to the skin via the infusion set, it is also to be appreciated that fluid may be pumped from the skin into feed tube via the infusion set (*i.e.*, in an opposite direction), for sampling of body fluids. The two housing portions **14, 16** may be formed from plastic, or other suitable material by molding or other fabrication process.

[00047] With particular reference to **FIGURE 1**, the connector housing **16** includes a central portion **26,** which receives the feed tube **20** at least partially therethrough. Specifically, the central portion defines a bore **28** with a central axis **x.** **FIGURE 1** shows the feed tube **20** extending the entire length of the bore **28**, although it is to be appreciated that the feed tube may end closer to the upstream end of the bore or be connected therewith by a fitting (not shown). Two resiliently flexible arms **30, 32** extend laterally from and generally parallel with the central portion **26** and are connected at a rearward (upstream) end **29** with the central portion **26**. (The terms rearward, forward, upper and lower, and the like are used herein with reference to the orientation of the infusion set components illustrated in FIGURE 1). The arms **30, 32** are thus positioned 180° apart, one on either side of the central portion **26** and are aligned generally parallel therewith.

[00048] Ends of the respective flexible arms **30, 32** define resilient, outwardly projecting hooks **34, 36** for releasably locking the connector housing **16** to the cannula housing **14**. The hooks project forward of the central portion **26**. When a user grips the arms **30, 32** and squeezes them between his fingers, the distal ends of the arms flex inwardly, bringing the hooks **34, 36** closer together. The hooks are received in corresponding internal slots **44, 46** of the cannula housing (see **FIG. 2)** and engage suitably shaped and positioned shoulders **48, 50,** respectively. During

insertion, the hooks **40, 42** function as camming surfaces, causing the arms **30, 32** to flex inwardly and allowing the hooks **34, 36** to snap past the shoulders **48, 50**, automatically locking the connector housing **16** to the cannula housing **14** as the parts **14, 16** are advanced towards each other. To release the connector housing **16** from the cannula housing **14**, the arms **30, 32** are pressed inwards while the connector housing **16** is retracted from the cannula housing **14**.

[00049] The connector housing **16** is axially symmetrical, allowing the connector housing to be connected with the cannula housing **14** in one of two orientations, either as shown in **FIGURE 1**, or flipped 180°.

[00050] A forward (downstream) end **62** of the central portion **26** is selectively received within a forward (upstream) end **63** of a corresponding projection **64** on the cannula housing **14**. The projection **64** is shaped for guiding receipt of at least the downstream end of the central portion. Specifically, the projection defines a bore **65**, which extends axially through the projection. An interior wall **66** of the bore may be slightly tapered and matches the taper of an exterior surface **68** of the central portion **26**.

[00051] As can be seen from **FIGURE 1**, the hooks **34, 36** on the arms project forwardly of the cylindrical central portion **26** of the body portion, although it is also contemplated that the hooks may extend no further than the cylindrical central portion or be set back therefrom.

[00052] With reference to **FIGURES 3-5** the cannula housing **14** receives a cannula insertion needle **70** in the form of a fine bored tube. The canula needle serves to introduce the cannula into the user's skin and is withdrawn after the catheter has been inserted. The cannula needle is selectively insertable into a seal or septum **78** in the cannula housing, such as a cylindrical, self-sealing silicone seal. The septum seals a hole formed in the catheter **15** by needle at an upper end **80** thereof. The self-sealing septum provides a liquid and air seal towards the environment when the needle **70** is retracted from the septum and further provides a liquid and air seal around the needle when inserted through the septum.

[00053] As shown in **FIGURE 1**, the bore **65** of the cannula housing **14** extends between the forward end **63** of the projection and the septum **78**.

[00054] An annular stopper **84** is received within the bore **65**. The stopper encircles a tubular member, such as a tube **86**, which extends axially along the bore **65** between the forward end **63** of the projection and the catheter entrance **80**. The stopper defines an interior passage **87 (FIG 1A)**. The stopper is formed from a resiliently flexible material and sealingly engages an exterior surface of the tube while also sliding relative thereto. The stopper preferably defines a valve **88** at a forward end thereof, such as a flap valve.

[00055] The stopper **84** is biased to the position shown in **FIGURE 1** by a biasing member **90**, such as a spring. The spring encircles the tube **86** and is held under compression between the stopper and the septum **78**. Optionally, a flange (not shown) at the forward end **63** of the bore **65** prevents the stopper **84** from exiting the bore **65**. In the position shown in **FIGURE 1**, the flap valve **88** is in a closed position, sealing the tube **86** from the atmosphere.

[00056] When the central member **26** is inserted into the bore **65**, the forward end **62** of the central member engages the stopper **84** and pushes it rearwardly into the projection, against the bias of the spring, to the position shown in **FIGURE 2**. The tube **86** opens the flap valve **88** in the process (for example, pushes apart four flexible flaps **92** which make up the valve) and enters the bore **28** of the connecting member and passes into the feed tube **20**. Fluid can then flow from a first passage **93** defined by the feed tube **20** (and/ or by the bore **28** if the feed tube **20** does not extend entirely along the bore **28**) into an interior passage **94** of the tube **86** and thence to the catheter **15**. While the tube **86** is coupling with the bore **28** to form a connecting passageway, the hooks **34, 36** are entering the respective internal slots **44, 46** of the cannula housing and engaging the shoulders **48,50**. With the two components **14, 16** thus locked together the stopper maintains a seal between the tube **86** and the forward end **62** of the central portion (and/or the feed tube if it extends forwardly

of the forward end **62**) and prevents leakage of liquid from the housing **10**. Alternatively, at least one of the tube **86** and the bore **28** is tapered such that the adjacent surfaces of the tube **86** and bore **28** (or feed tube **20**) frictionally engage each other during coupling of the housing portions **14, 16** to provide a seal therebetween.

[00057] With reference to **FIGURE 7**, an alternative embodiment of an infusion set **100** includes a two-part assembly or housing **110** with a generally planar configuration when assembled. A soft cannula or catheter **112** extends from a first portion or cannula housing **114** of the assembly and is received through the skin (not shown) of a user of the infusion set. The cannula **112** is formed from a soft plastic material and has a central bore **115** through which a medicament, such as insulin, or other liquid to be infused is supplied from the assembly **110** into the user's body. A second, connector portion or needle housing **116** of the assembly **110** is configured for releasable interlocking with the cannula housing **114** in a similar manner to that described for the embodiment of **FIGURES 1-6**. The first portion **114** of the housing **110** is designed to remain on the user's skin for extended periods, while the second portion **116** is removed at intervals for bathing or other purposes. The needle housing **116** is of a thinner cross section ***d*** than the cannula housing.

[00058] The needle housing **116** carries a needle **118,** which is fluidly connected with a feed tube **120** analogous to the feed tube **20.** The feed tube **120** supplies the medicament to be injected from an infusion pump (not shown), or other supply source, to the needle **118**. The feed tube **120** is fluidly connected with the infusion pump via a Luer connection **122** or other suitable releasable connection. The two housing portions **114, 116** may be formed from plastic, or other suitable material by molding or other fabrication process.

[00059] With reference also to **FIGURES 8-11**, the needle housing **116** includes a body portion **126,** which is shaped to provide a cover for the needle **118** and to receive the feed tube. Specifically, the body portion includes a central portion **128,** in the form of a generally cylindrical tube

with a central axis **x,** and two resiliently flexible arms **130, 132**, which extend laterally from and generally parallel with the central portion **128**. The arms **130, 132** are connected at a rearward (upstream) end **129** of the body portion with the central portion **128**. (The terms rearward, forward, upper and lower, and the like are used herein with reference to the orientation of the infusion set components illustrated in **FIGURE 7**). The arms **130, 132** are thus positioned 180° apart, one on either side of the needle **118** and are aligned generally parallel therewith.

[00060] A pair of resilient, hook-shaped tabs **134, 136** extend from distal ends of the respective flexible arms **130, 132**, on either side of the needle, for releasably locking the needle housing **116** to the cannula housing **114** and project forward of the central portion **128**. The two arms **130, 132** include finger-gripping regions **138**, respectively, defined by serrated edges of the arms **130, 132**. When a user grips the finger-gripping regions **138** and squeezes them between his fingers, the distal ends of the arms flex inwardly, bringing the tabs **134, 136** closer together. Distal ends of the tabs **134, 136** define hooks **140, 142** having outwardly extending ends. The hooks are received in corresponding internal slots **144, 146** of the cannula housing (see **FIGS 10** and **11**), and engage suitably shaped and positioned shoulders **148, 150,** respectively. During insertion, the hooks **140, 142** function as camming surfaces, causing the arms **130, 132** to flex inwardly and allowing the hooks **140, 142** to snap past the shoulders **148, 150**. To release the needle housing **116** from the cannula housing **114**, the arms **130, 132** are pressed inwards while the needle housing **116** is retracted from the cannula housing **114**.

[00061] Returning to **FIGURES 7-9,** the central portion **128** of the needle housing comprises an axial, generally cylindrical tube for protecting the needle **118**. The tube **128** protrudes above and below the rest of the body portion such that the profile of the body portion is substantially the same on both upper and lower surfaces **154, 156** thereof. This allows the needle housing **116** to be connected with the cannula housing **114** in one of two orientations, either as shown in **FIGURE 7**, or flipped 180°.

[00062] An axial bore **158** is formed within the tube **128**, in which the needle **118** is concentrically positioned. The bore **158** has an opening **160** at an end **162** of the tube **128** facing the cannula housing **114**. The tube **128** is slidingly received on a mating projection **164** on the cannula housing when the tabs **134, 136** are engaged with the respective cannula housing shoulders **148, 150**. The projection **164** is shaped for guiding receipt of the tubular portion **128**. Specifically, an interior wall **166** of the tubular portion bore **128** may be slightly tapered and matches the taper of an exterior surface **168** of the projection **164**.

[00063] As can be seen from **FIGURE 7**, the hooks **140, 142** on the tabs project forwardly of the cylindrical portion **128** of the body portion, although it is also contemplated that the tabs may extend no further than the cylindrical portion or be set back therefrom.

[00064] With reference to **FIGURE 7** and also to **FIGURE 12**, the cannula housing projection **164** carries a needle guide **172**, preferably formed from metal or alloy, such as stainless steel. The needle guide **172** includes an open funnel portion **174**, which faces outwardly from the canula housing, and a tubular portion **176** connected therewith, which is fluidly connected with the cannula **112**. A seal or septum **178**, such as a cylindrical, self-sealing silicone seal, may be seated upstream of the funnel portion **174** of the needle guide **172**, as shown in **FIGURE 12**, or downstream of the needle guide. The self-sealing septum provides a liquid and air seal towards the environment when the needle **118** is retracted from the septum and further provides a liquid and air seal around the needle when inserted through the septum.

[00065] As shown in **FIGURE 12**, the cannula housing **114** defines an interior bore **180** therethrough, which is shaped to house the cannula, needle guide **172** and seal **178**. The cannula housing bore **180** extends axially through the projection **164**. As can be seen, the bore **180** includes a series of interconnected sections of increasing internal diameters, a first narrow cylindrical section **182**, which houses an upstream end **183** of the cannula, a second, slightly wider cylindrical section **184**, which houses the

tubular portion **176** of the needle guide, a third, tapered conical section **186**, which follows the shape of the funnel portion **174** of the needle guide, a fourth cylindrical section **188** of the same diameter as the widest end of the conical section **186**, and a fifth, cylindrical section **190**, which is of slightly larger diameter than the fourth section. The seal **178** is shaped such that it fits snugly in the fifth section **190**. The fourth section **188**, being of slightly smaller diameter than the fifth section, spaces the seal from the needle guide. This section may be eliminated, if desired.

[00066] To assemble the parts of the cannula housing **114** of this embodiment, the cannula **112** and needle guide **172** are joined together and inserted into the bore **180** from the widest end. Then the seal **178** is simply press fit into the fifth section **190** of the bore. An adhesive may be applied to the edges of the seal and/or to the sides of the fifth section to secure the seal in the bore **180**.

[00067] With reference to **FIGURES 7** and **11**, the cannula housing **114** includes a shelf **200** which extends generally parallel with a spaced below the projection **64** and defines a longitudinal concave trough **202**. The trough **202** is shaped to receive the cylindrical portion **128** of the needle housing body therein. Since the body portion has essentially the same profile on both its larger surfaces (top and bottom surfaces **154, 156** in **FIGURE 12**), the cylindrical portion enters the trough when the needle housing is connected in either of two orientations. The rest of the body portion and tabs rest on the adjacent flat upper surfaces **204, 206** of the shelf.

[00068] **FIGURES 13** and **14** show an insertion set **210** which can be used with the cannula housing **114** to insert the cannula into the skin of the user. The insertion set has a longer needle **212** than is used with the needle housing **116**, which extends to the end of or slightly beyond the distal tip **214** of the cannula when fully inserted (See **FIG. 15**). As can be seen from **FIGURE 13**, the cannula may be inserted in to the skin prior to placing the septum in the cannula housing bore. This avoids potential damage to the septum by the insertion needle **214**. Once the cannula has

been positioned in the users body, the insertion set **210** is removed and the seal **178** inserted in the cannula housing. Or, the seal can be inserted and glued into the bore prior to insertion of the cannula into the skin for convenience. A cover **216** protects the tip of the needle **214** when not in use (**FIG. 14**).

[00069] With reference to **FIGURES 1-7,** and **16-20**, the infusion set of either embodiment is held in position by the attachment system **11**, which in the preferred embodiment, comprises an adhesive patch or tape **220**. Preferably, the patch is of a multi-layer construction, and includes a structural support layer **222**, for providing structural upport to the infusion set, such as a layer of a non-woven material, *e.g.*, polyester. The support layer has a layer **224** of an adhesive on its lower surface (see **FIG. 19**), such as a pressure sensitive adhesive (PSA), *e.g.*, an acrylic, for attaching the layer firmly to the wearer's skin. A suitable structural layer **222** is an embossed non-woven polyester fabric, about 1.5 mm in thickness, sold under the tradename Hypofix. Attached to, and extending at least partially beyond the periphery of the non-woven material layer **222** is a breathable layer **226** formed from a wicking material, such as a transparent polyurethane sheet. A suitable breathable layer **226** is a transparent polyurethane tape, about 1.0 mm in thickness, sold under the tradename IV 3000. In an alternative embodiment, a breathable layer is formed from a silicone elastomer or hydrocolloid. The polyurethane, or other breathable material, while not necessarily having as great a structural strength as the support layer, preferably has a greater capacity for absorbing moisture from the skin- *i.e.*, wicking it away, keeping the skin relatively dry. The breathable layer may have pores **228** formed through the material, as shown in **FIGURE 20**, to aid or provide the wicking function. The pores are sufficiently small to allow air and moisture vapor to pass through but inhibit bacteria from getting in to the skin. Alternatively, the breathable layer is air and/or moisture permeable without requiring pores, such as a hydrocolloid which allows one-way transport of moisture through the layer.

[00070] The porous layer **226** thus provides a bacteria-impermeable, water and air permeable barrier. The breathable layer **226** has a layer **230** of adhesive on its lower surface (See **FIG. 19**) for adhering the layer **226** to the layer **222** and to the wearer's skin in those areas where the breathable layer extends beyond the support layer. The adhesive may be a PSA, as for the first adhesive layer **224**. The breathable layer is thus attached to the skin in an area **230** surrounding the point of entry to the skin of the cannula (which is the area where bacterial infection is most likely) while the support layer, with lower vapor transmission but greater strength, is attached to the skin in an area away from the cannula entry, where infection is less likely, to support the infusion set.

[00071] The infusion set is attached to the breathable layer **226** by an adhesive layer, such as a layer of double sided transfer tape **234**, or other suitable attachment material, which is positioned over the support layer, as can be seen from **FIGURE 17**. The patch thus has a multi-layer construction in use, with three, adhesively connected layers **222**, **226**, and **234** in a region below the infusion set **1, 100** and a single layer **226** in a region away from the infusion set, adjacent the cannula entry. The layers **226** and **222** may themselves be formed from more than one layer of material.

[00072] Release liners **236, 238, 240**, such as silicone wax coated paper, are attached to the upper and lower surfaces of the patch to protect the surfaces until use. The lower release liner **240** has an aperture **242** therein which receives the cannula therethrough, and may be perforated to allow forward and rear portions **240A** and **240B** to be removed separately. The release liners are removed prior to use. As shown in **FIGURE 18**, the upper release liner may be in two portions **236, 238**.

[00073] The structural layer **222** may be generally rectangular, as shown in **FIGURES 16** and **20**, with side edges **242, 244** extending to the periphery of the breathable layer. Or, in an alternative embodiment, shown in **FIGURES 21-24**, may be bounded on all sides by a portion of the breathable layer. **FIGURE 21** shows the structural layer **222** as circular,

although other shapes which provide sufficient support to the infusion set are also contemplated. In this embodiment, the remaining layers are the same as for **FIGURE 16**.

[00074] In both embodiments, the support layer **222** is preferably as large, or slightly larger than the infusion set so that it provides support for the entire bottom surface of both parts of the housing.

[00075] Tabs **246** on the release liners provide for easy removal of the release liners.

[00076] With reference now to **FIGURES 25** and **26**, a small hole **247** is formed in the breathable layer **226** during penetration of the cannula into the skin **248**. To inhibit ingress of infectious microorganisms or dirt through the hole **247** in the layer **226** where the cannula penetrates, a protective layer or antimicrobial film **249** may be placed over the cannula in the area of the insertion region, after insertion of the cannula into the skin. The protective layer **249** may be formed from the same material as the layer **226** - *e.g.*, a polyurethane sheet about 1mm in thickness with an adhesive PSA layer for adherence on to the layer. A release liner (not shown) may be provided on the bottom and optionally the top of the layer **249** to protect the layer until use. The two layers **226, 249** when sandwiched together, provide for air and moisture vapor to pass through but inhibit bacteria from getting in to the skin. The porous combination layer **226**, **249** thus provides a bacteria-impermeable, water and air permeable barrier in a similar manner to the layer **226** alone, but provides additional protection in the area of cannula entry.

[00077] As can be seen from **FIGURES 1-7,** and **12**, in particular**,** the infusion set, when assembled, has a bullet-shaped cross section, with relatively flat upper and lower surfaces, which keeps the device close to the user's skin. It can be manufactured to a small size (about 2-3cm in length and width, or less) while nevertheless being easy to manipulate by the wearer.

[00078] It is also contemplated that the structural layer **222** be omitted and that the breathable layer **226** be of sufficient strength to support the infusion set. For example, **FIGURE 3** shows a tape **220'** in which the top layer **226'** is an elastomeric material, such as a silicone elastomer, which may be moisture permeable or non-moisture permeable or a hydrocolloid which is one-way permeable. In this embodiment, the layer **226'** is mechanically rather than adhesively attached to the cannula housing **14, 114,** although it is also contemplated that an adhesive layer may be employed, as discussed above, either alone, or in combination with a mechanical attachment means. Suitable mechanical means for attachment include O-rings, snaps, or the like.

[00079] As shown in detail in **FIGURE 3A**, for example, the top layer **226'** defines a cavity **250** shaped to receive a lower surface **260** of the infusion set **1, 100**. The infusion set is held in the cavity by an O-ring **252** seated in a groove **254** in the cannula housing **14, 114'** and/or a corresponding groove **256** in the cavity **14**. Alternatively, layer **226'** may be attached to the infusion set **1, 100** by an adhesive layer **230'**, analogous to layer **230**, as discussed above. A layer of an adhesive, such as a PSA, attaches the layer **226'** to the skin and is protected, prior to use by a release liner (not shown).

[00080] Suitable silicone elastomers for the layer **226'** are formed from (A) organopolysiloxane polymers having a siloxane backbone being end-blocked which may have at least two silicon-bonded groups R, wherein R denotes an olefinically unsaturated hydrocarbon substituent, an alkoxy group or a hydroxyl group, (B) a cross-linking organosilicon material preferably having at least 3 silicon-bonded reactive groups, (C) a catalyst capable of promoting the reaction between the silicon-bonded groups R of compound (A) and the silicon-bonded reactive group of compound B, although other silicone elastomers are also contemplated.

[00081] Suitable hydrocolloid adhesives are disclosed, for example, in U.S. Patent No. 4,551,490. For example, the hydrocolloid may be formed from a mixture of mineral oil, polyisobutylene, styrene-isoprene-styrene

(SIS) rubber, and antioxidant, to which a carboxymethylcellulose, cross-linked sodium carboxymethylcellulose, tackifier, and ethylene propylene rubber are added in stages.

[00082] While the adhesive patch **220** has been described with particular reference to an infusion set, it will be appreciated that other devices may be adhered to the skin with the patch. The patch may be made with appropriate dimensions for securing the desired device. It is also contemplated that the infusion set may be attached to the skin with an elastomeric rubber with adhesive applied as an alternative to the non - woven tape.

[00083] With reference now to **FIGURES 27** and **28,** a third alternative embodiment of an infusion set is shown, with similar parts indicated by a prime(') and new parts given new numbers. In this embodiment, a needle housing **116'** is analogous to the needle housing of **FIGURE 7**. A cannula housing **114'** is similar to the cannula housing **114**, but differs in that a projection **164'** has a bore **180'** which is shaped to receive a seal cartridge **350** therein, in place of the needle guide and seal of **FIGURE 1**. The seal cartridge includes a cylindrical portion **352**, which receives a seal **354**, similar to the seal of **FIGURE 7**. The seal may be introduced to the cylindrical portion via a bore **356** formed in the cylindrical portion or may be inserted into the cylindrical portion during molding. A hollow tube **358** extends from one end of the cylindrical portion for connection with the catheter **112'**. A conical needle guiding member **360** is defined in other end of the cylindrical portion. The seal cartridge defines a longitudinal central bore **362**, generally perpendicular to the bore **356,** for receiving the needle **118'** of the needle housing therethrough. The needle is long enough to pass through the seal and into the tube **358** when the two parts of the housing are connected together.

[00084] The open end of the projection **164'** defines a number of circumferentially spaced flexible tabs **366**, with slits **368** therebetween. The flexible tabs **366** define inwardly projecting hooks **370**. The hooks snap fit over the seal cartridge as it is inserted into the open end of the

projection and seat in a circumferential locking shoulder or grove **376** defined on the seal cartridge between the cylindrical portion **352** and the needle guiding member **360**.

[00085] Alternatively, the tabs may be replaced by a smooth sided projection with the seal cartridge attached to the inner surface of the projection by adhesive, welding, or other suitable means.

Having thus described the preferred embodiment, the invention is now claimed to be:

1. An infusion set **(1, 100, 100')** and attachment system **(11)** combination characterized by:

an infusion set **(1, 100, 100')** and a conformable patch **(220, 220')** for attaching the infusion set to the skin of a wearer, the infusion set including:

a first housing portion **(14, 114, 114')** connected to a top layer **(226, 226')** of the patch;

a second housing portion **(16, 116, 116')** selectively interconnectable with the first housing portion for forming a fluid passageway therebetween, the second housing portion being connected with a source of a liquid to be introduced to the wearer; and

a cannula **(15, 112, 112')** connected with the first housing portion for introducing the liquid to the wearer, the cannula passing through the patch when inserted into the wearer's skin **(S)**.

2. The combination of claim 1, further characterized by the patch including at least one of:

a first layer **(222)** formed from a structural material; and

a second layer **(226, 226')** formed from a moisture permeable material, the cannula passing through at least one of the first and second layers.

3. The combination of either one of claims 1 and 2, further characterized by the patch further including at least one of:

a layer **(230, 230')** of adhesive for attaching the patch to the wearer's skin; and

a layer **(234)** of adhesive for attaching the patch to the cannula housing.

4. The combination of claim 2, further characterized by:

the second layer **(226')** including a cavity **(250)**, the cavity being shaped to receive a lower surface **(260)** of the cannula housing.

5. The combination of claim 4, further characterized by:

an O-ring **(252)** for selectively attaching the cannula housing to the cavity, the O-ring being received in a groove **(254, 256)** formed in at least one of the cavity and the cannula housing.

6. The combination of claim 2, further characterized by:

the first layer being formed from a non-woven material.

7. The combination of claim 6, further characterized by:

the non-woven material including a polyester fabric.

8. The combination of any one of preceding claims 2-7, further characterized by:

the second layer being formed from a material selected from the group consisting of polyurethanes, hydrocolloids, and silicone elastomers.

9. The combination of claim 8, further characterized by:

the second layer including a moisture permeable silicone elastomer.

10. The combination of any one of preceding claims 1-9, further characterized by:

the second housing portion defining a first passage **(93)** which is selectively fluidly connected with the source; and

the first housing portion defining a second passage **(94)** for selectively coupling with the first passage to form the fluid passageway, the first housing portion including a sealing member **(84)** which is biased to a sealing position in which it seals the second passage, the sealing member being moved to a non-sealing position in which fluid flows between the first and second passages on coupling of the first and second housing portions.

11. The combination of claim 10, further characterized by:

the sealing member including a valve **(88)**, the combination further including a spring **(90)** which biases the sealing member to the sealing position.

12. The combination of either one of claims 10 and 11, further characterized by the first housing member including:

a projection **(64)** which defines a bore **(65)**, the sealing member **(84)** being movably mounted within the bore; and

a tube **(86)** carried within the bore and fluidly connected with the cannula, the second passage being defined by the tube, the sealing member sealing an end of the tube in the sealing position.

13. The combination of claim 12, further characterized by the second housing member including:

a generally cylindrical member **(26)** fluidly connected with the source of liquid which is received by the first housing portion bore, the generally cylindrical member defining the first passage.

14. The combination of claim 13, further characterized by the generally cylindrical member engaging the sealing member when the first and second housing members are coupled, and moving the sealing member to the non-sealing position.

15. The combination of claim 2, further characterized by:

the moisture permeable layer being positioned between the support layer and the infusion set.

16. The combination of claim 15, further characterized by:

a portion of the moisture permeable layer extending beyond the support layer and receiving the cannula therethrough.

17. The combination of any one of preceding claims 1-16, further characterized by:

connection means **(30, 32, 34, 36, 44, 46, 48, 50, 130, 132, 140, 142, 144, 146, 148, 150)** for selectively interconnecting the first and second housing portions.

18. The infusion set of claim 17, further characterized by:

the connection means including:

flexible arms **(30, 32, 130, 132,)** on one of the first and second housing portions, the arms defining hooks **(34, 36,140, 142)** ; and

slots **(44, 46, 144, 146)** on the other of the first and second housing portions which receive the hooks.

19. A method for supplying a liquid to a person characterized by:

attaching a patch to the skin of the person;

attaching a first housing portion to the patch;

inserting a cannula of the first housing portion through the patch and into the person's skin;

selectively coupling a second housing portion with the first housing portion to form a fluid flowpath **(93, 94)** therebetween which is fluidly connected with the cannula; and

feeding the liquid to the first housing portion, the liquid flowing along the fluid flowpath and into the cannula.

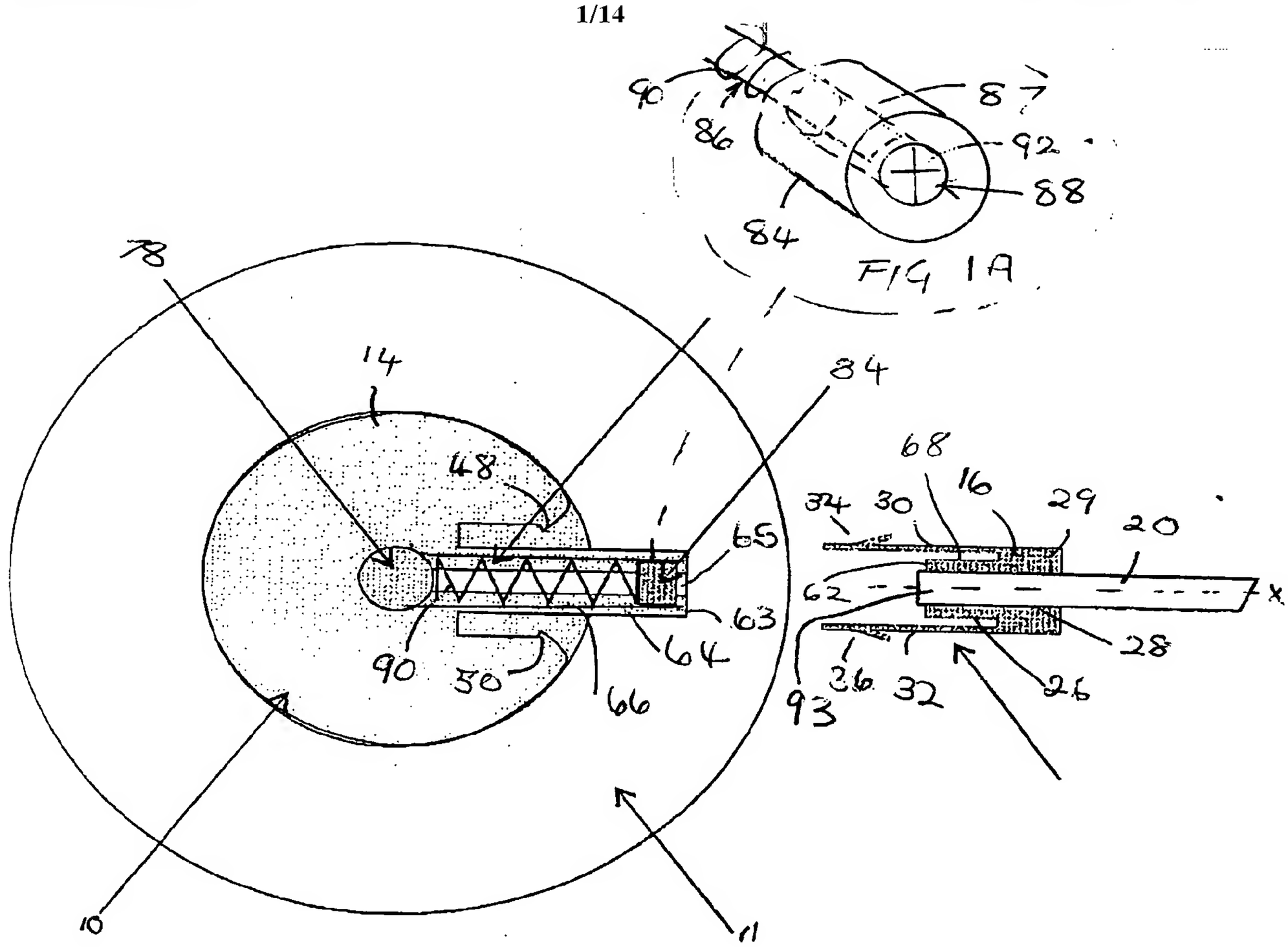

90
86
87
92
88
84
FIG 1A
78
14
84
48
68
16
34
30
29
20
65
62
63
64
28
90
50
66
93
36
32
26
10
11

FIG. 1

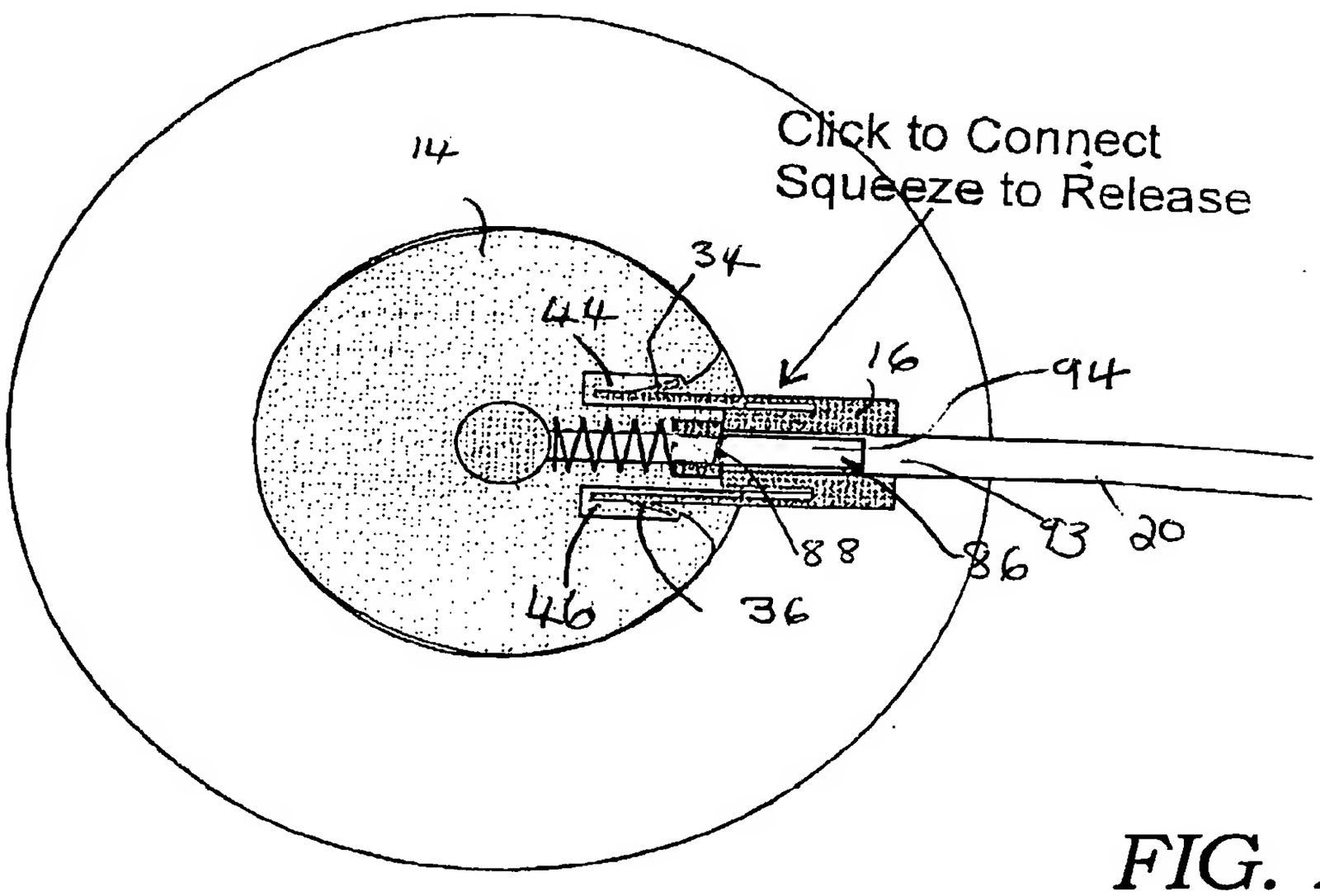

14
Click to Connect
Squeeze to Release
34
44
16
94
88
86
93
20
46
36

FIG. 2

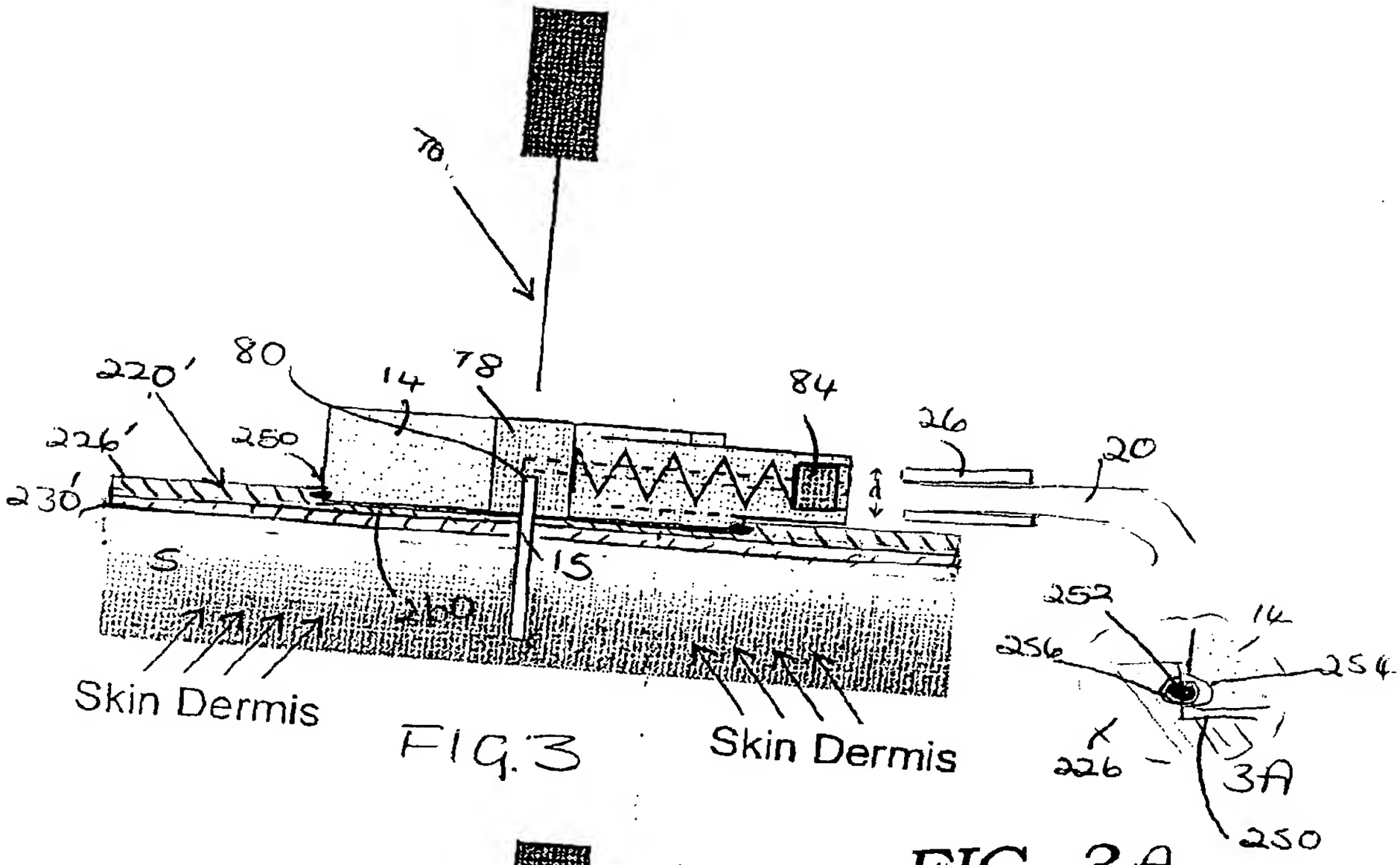


FIG. 3

FIG. 3A

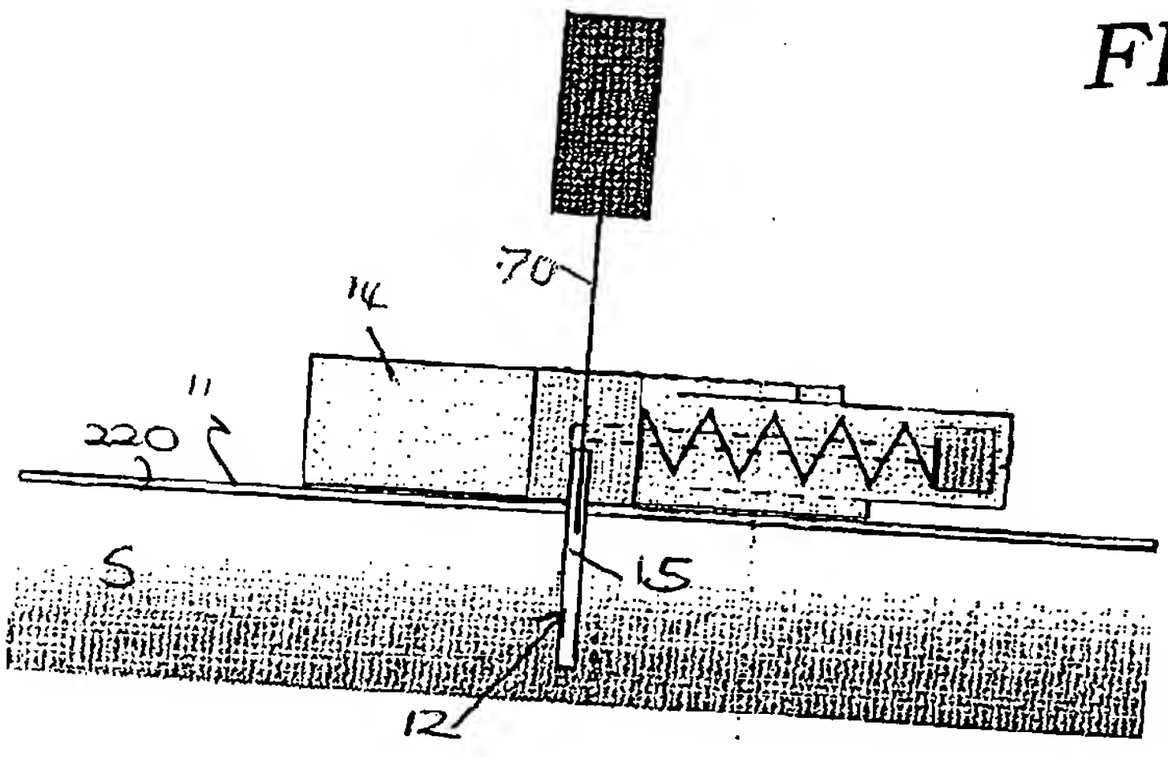


FIG. 4

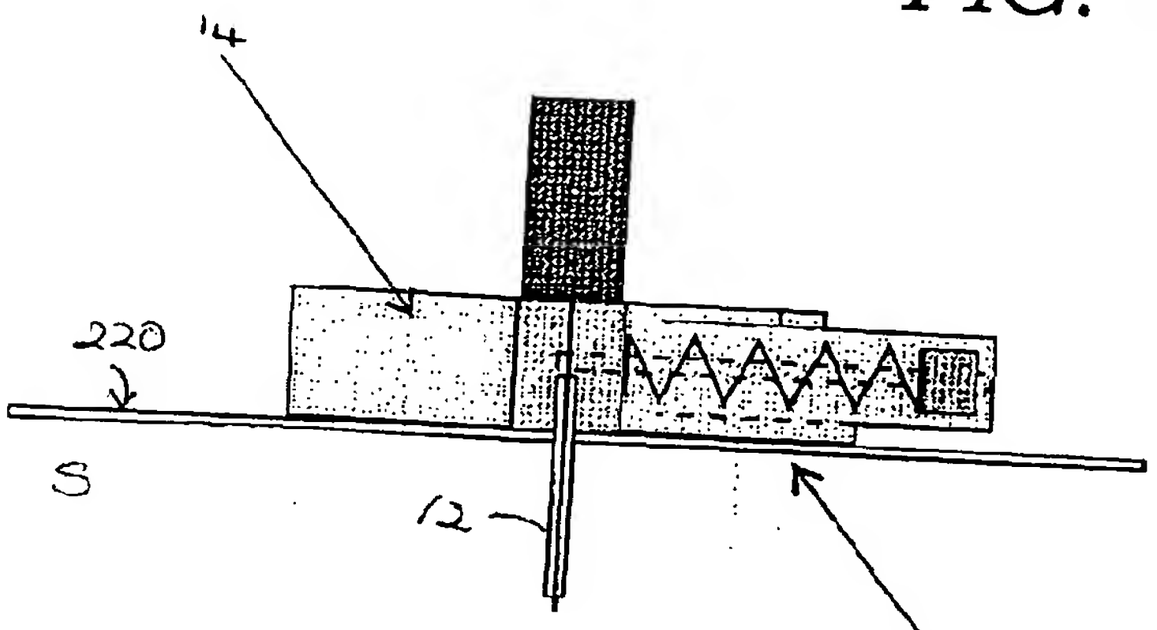


FIG. 5

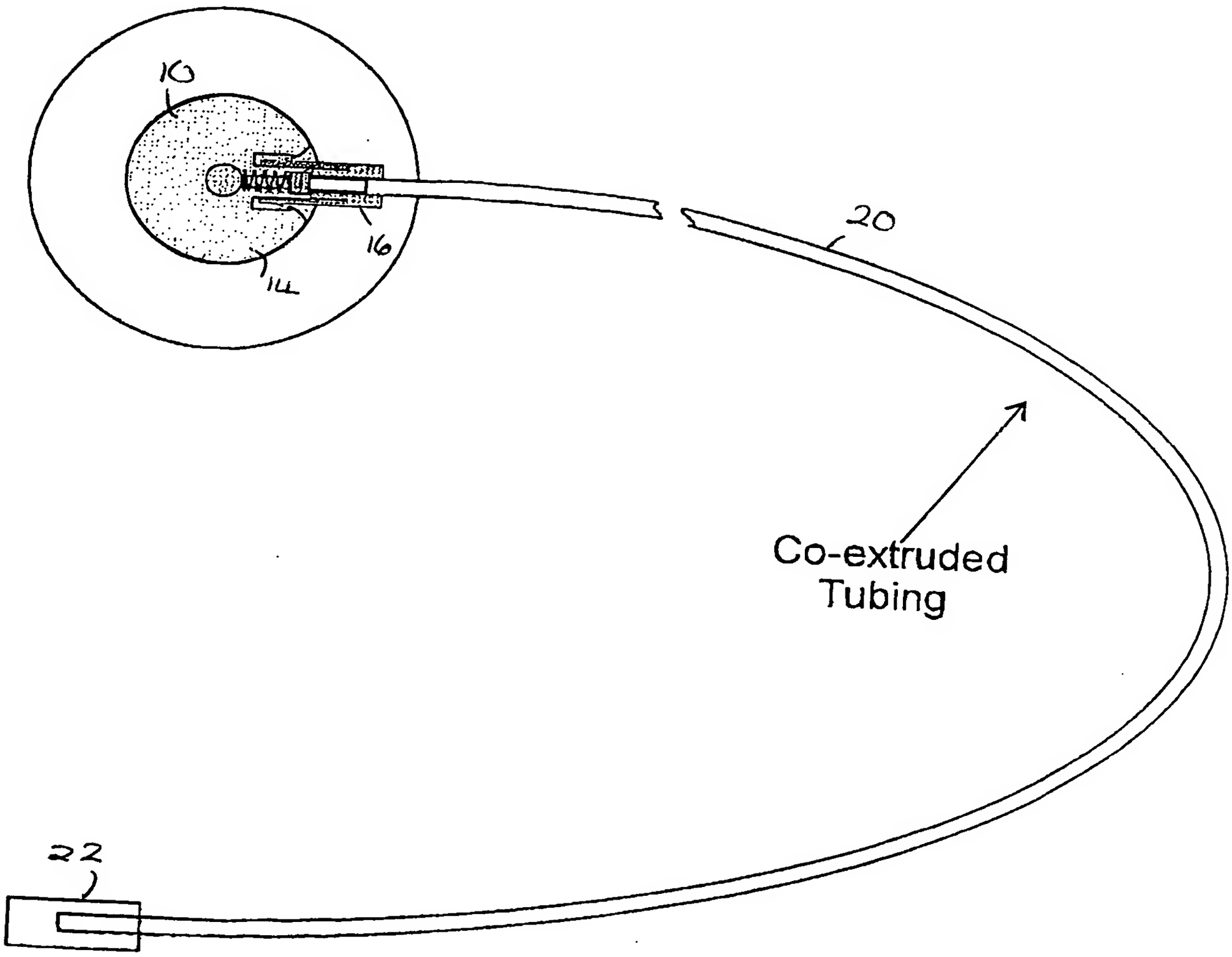


FIG. 6

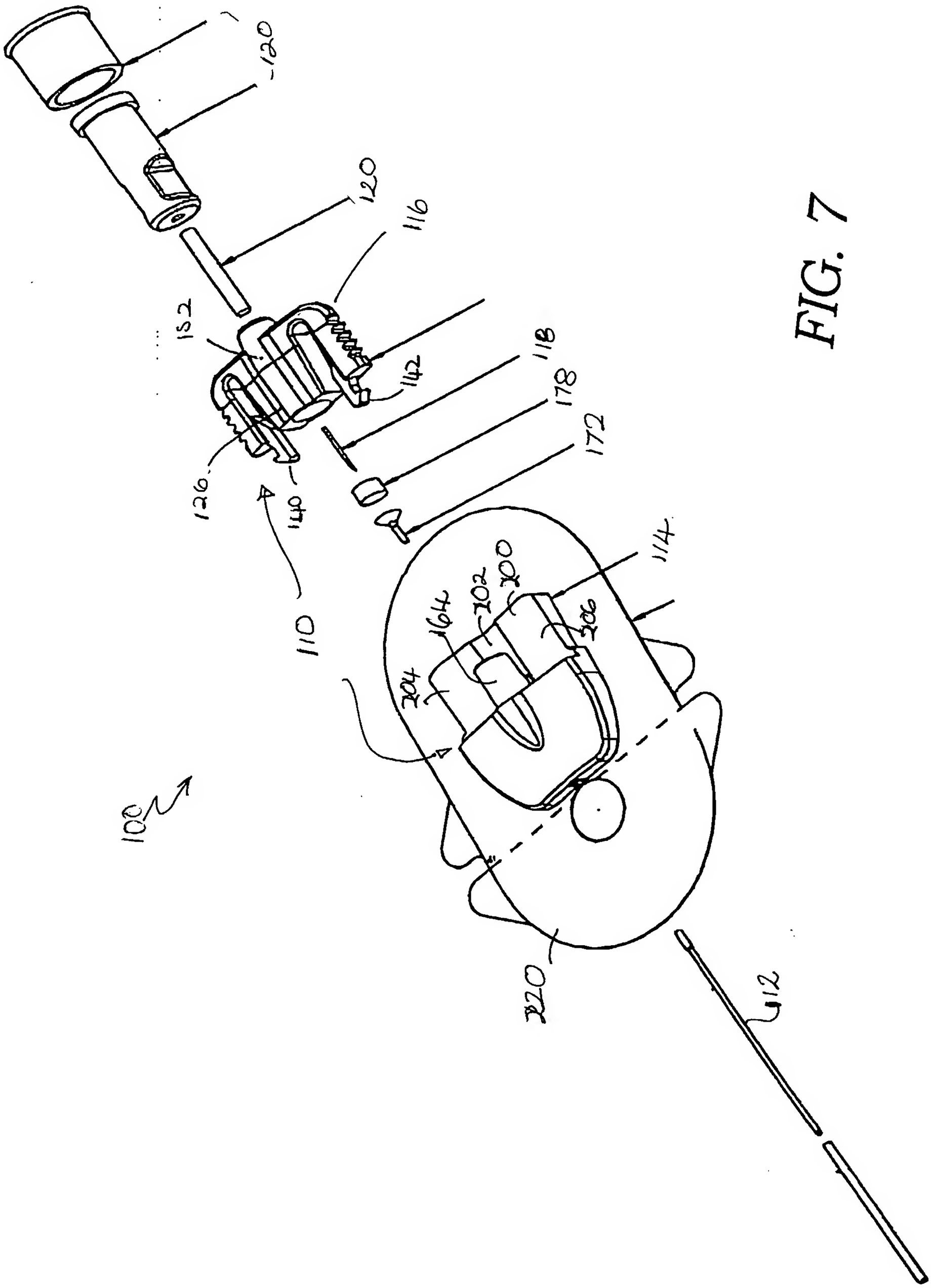

120
116
152
118
142
178
172
126
140
110
114
164
202
200
206
204
100
120
112

FIG. 7

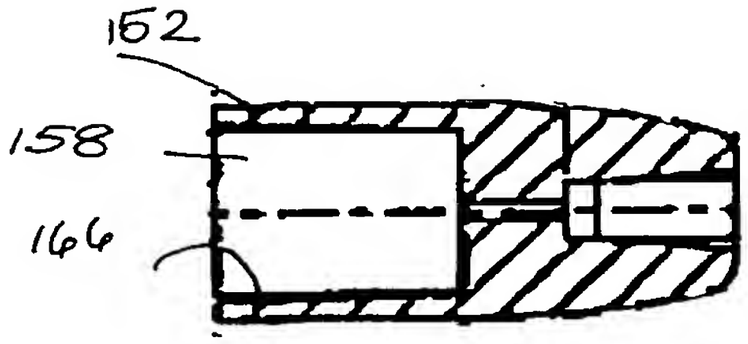


FIG. 8

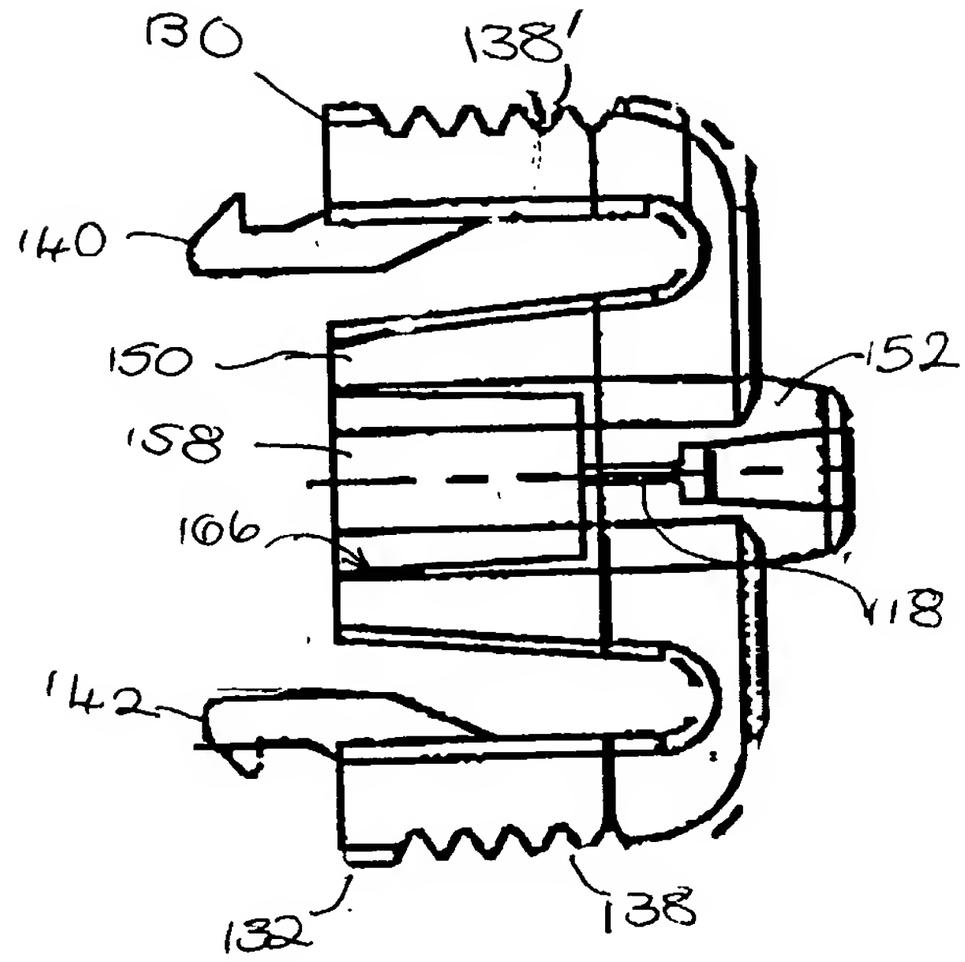
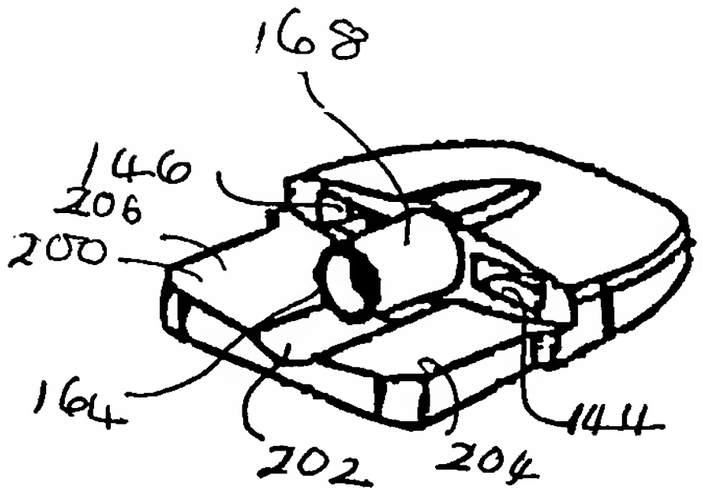


FIG. 9



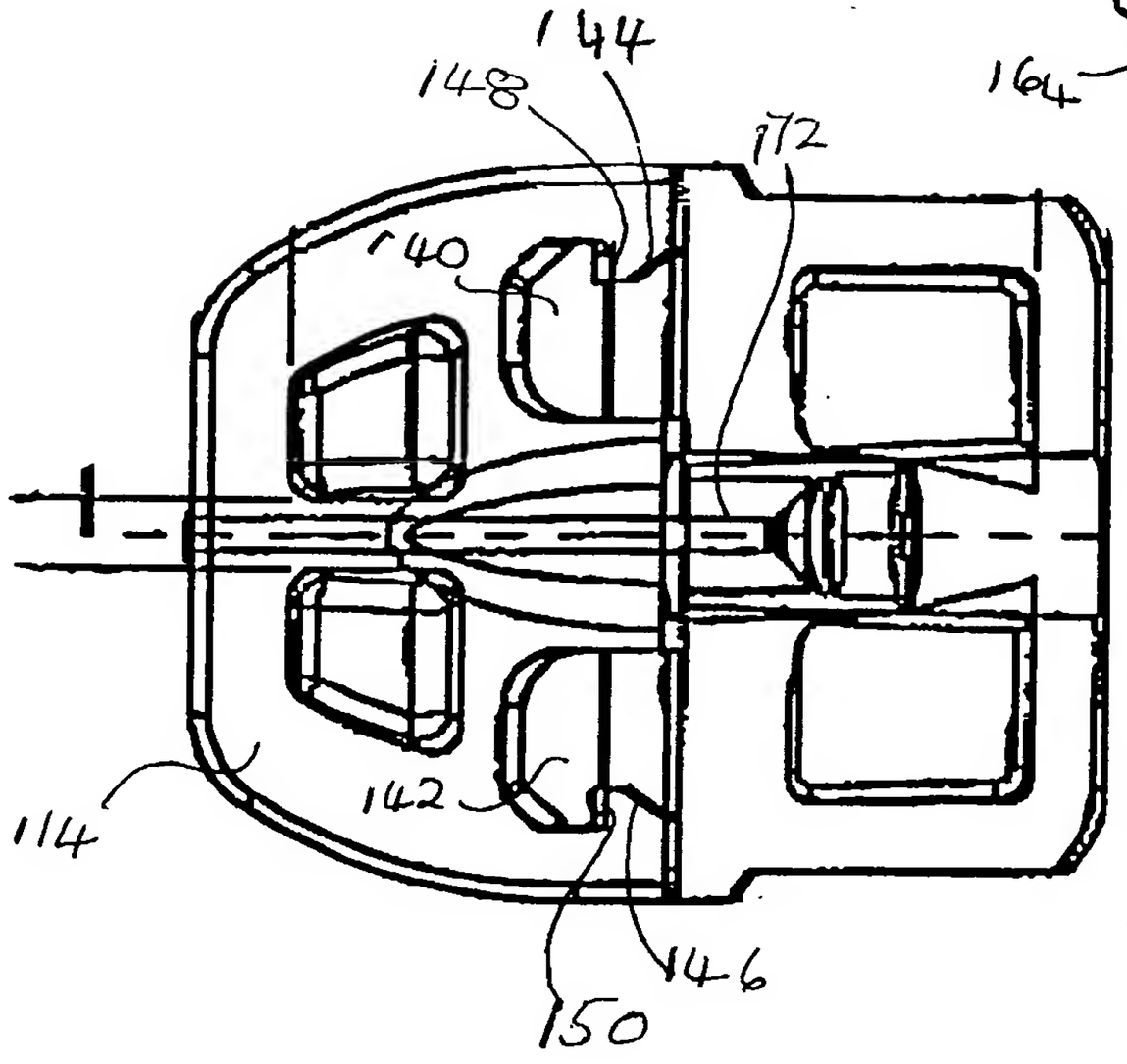


FIG. 11

FIG. 10

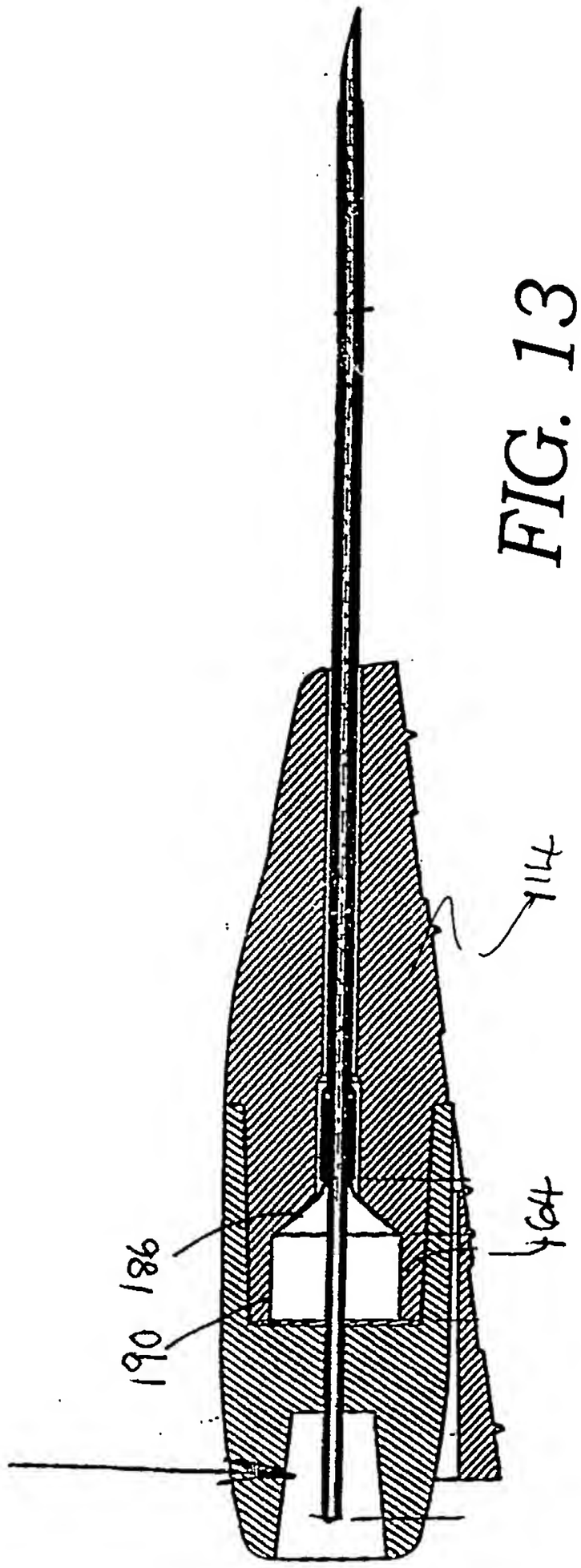

114
194
186
190

FIG. 13

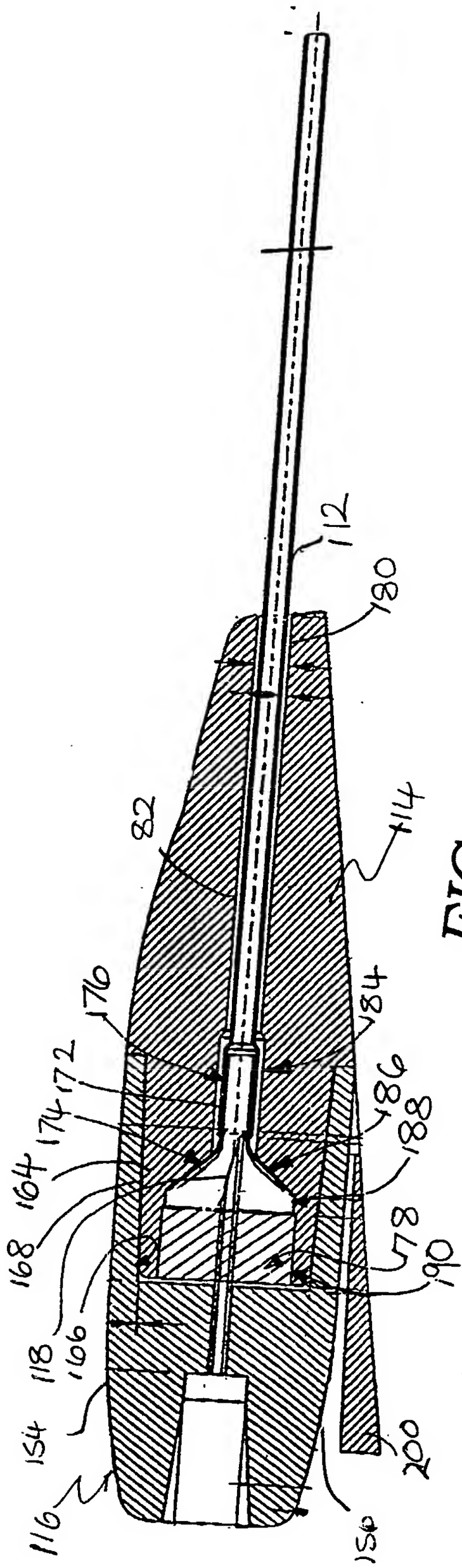

112
180
82
114
176
184
172
174
186
188
164
168
178
190
118
106
154
116
200
150

FIG. 12

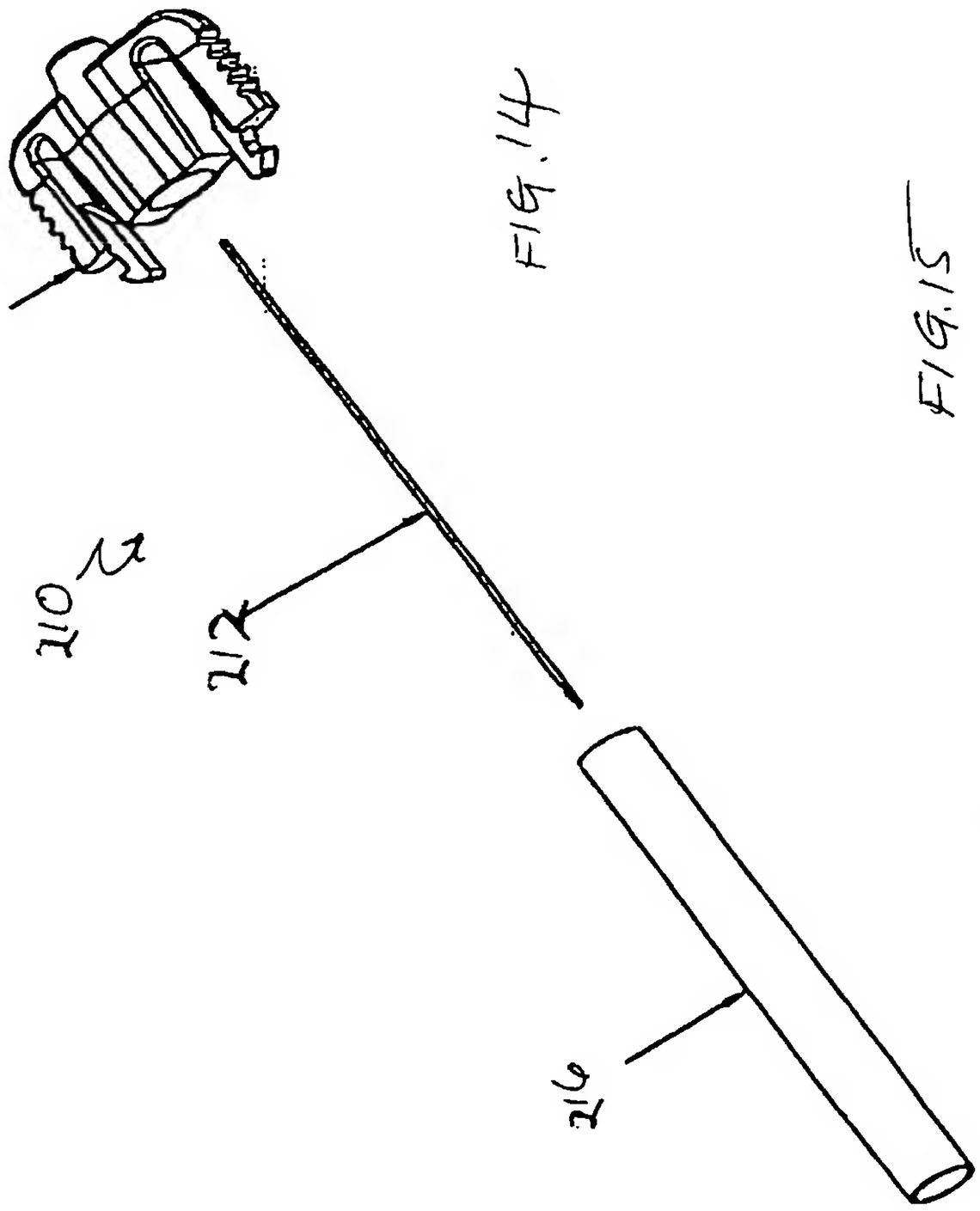


FIG. 14

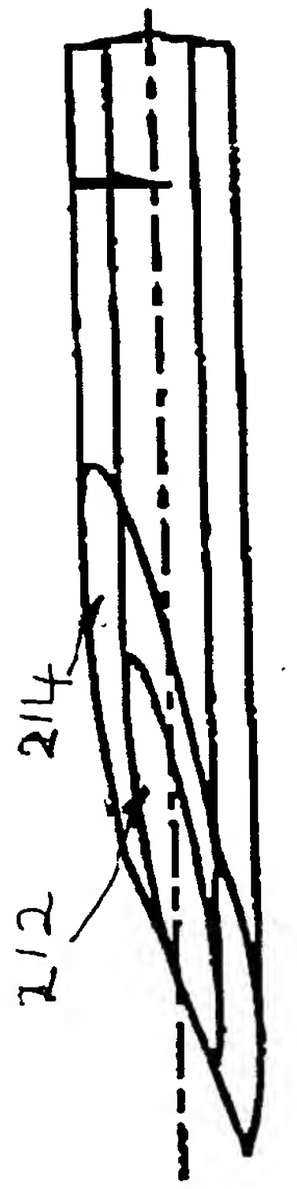


FIG. 15

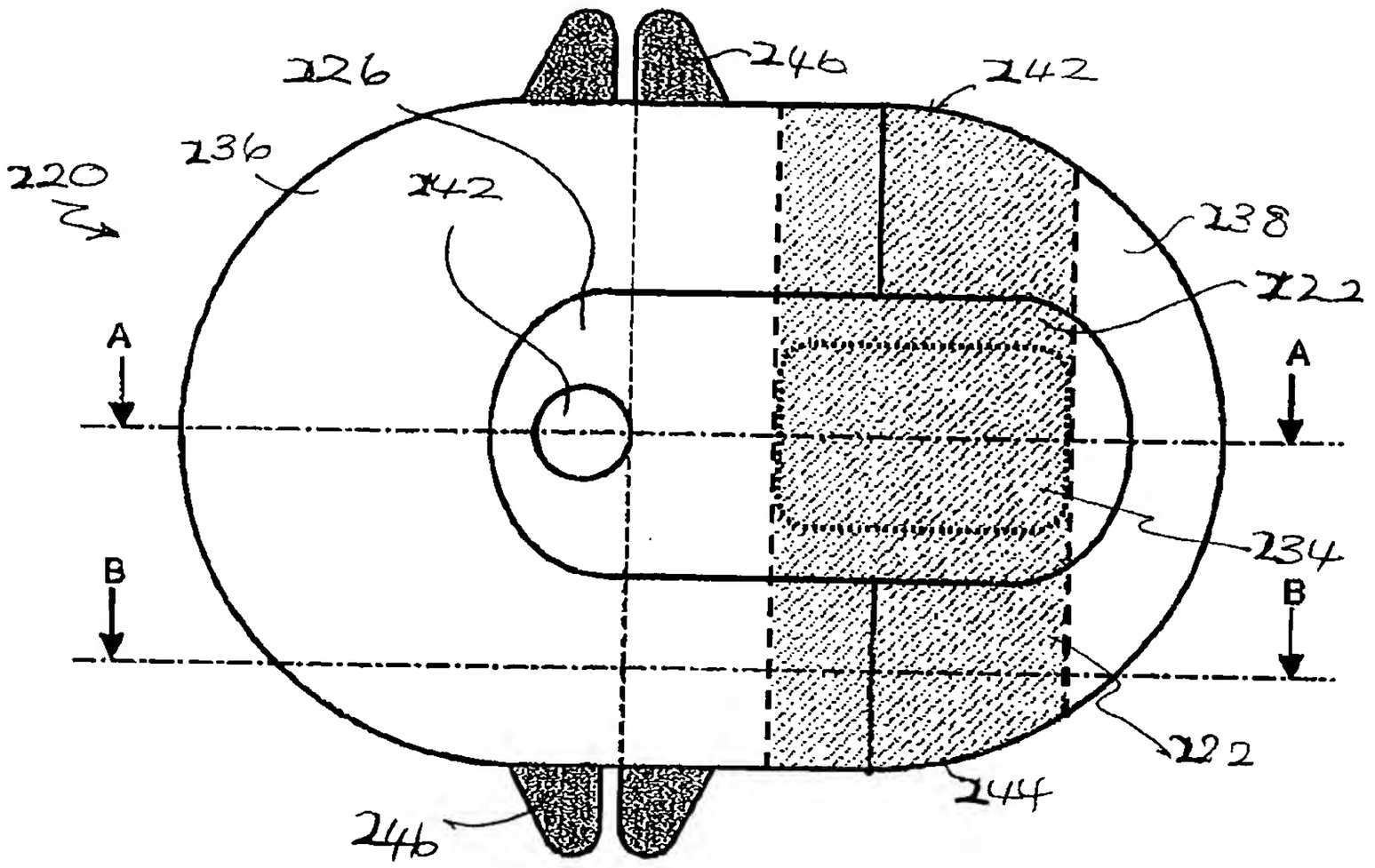


FIG 16

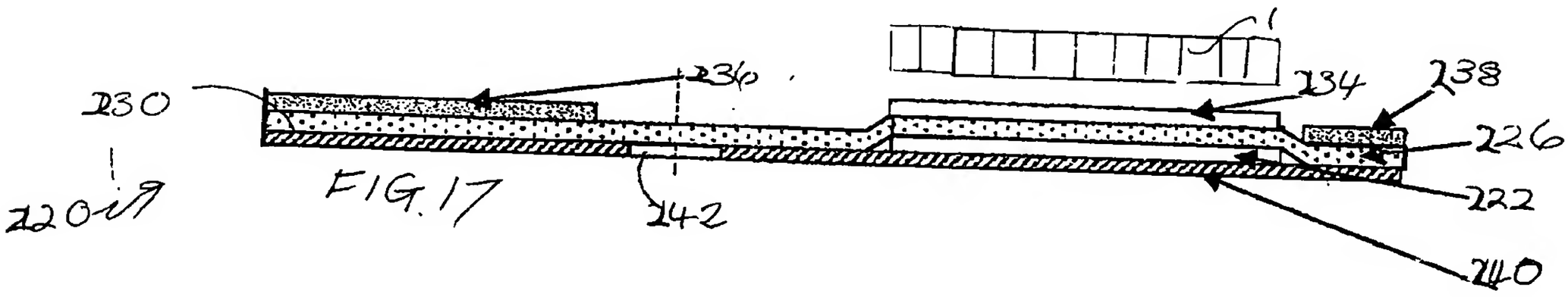


FIG. 17

View A-A

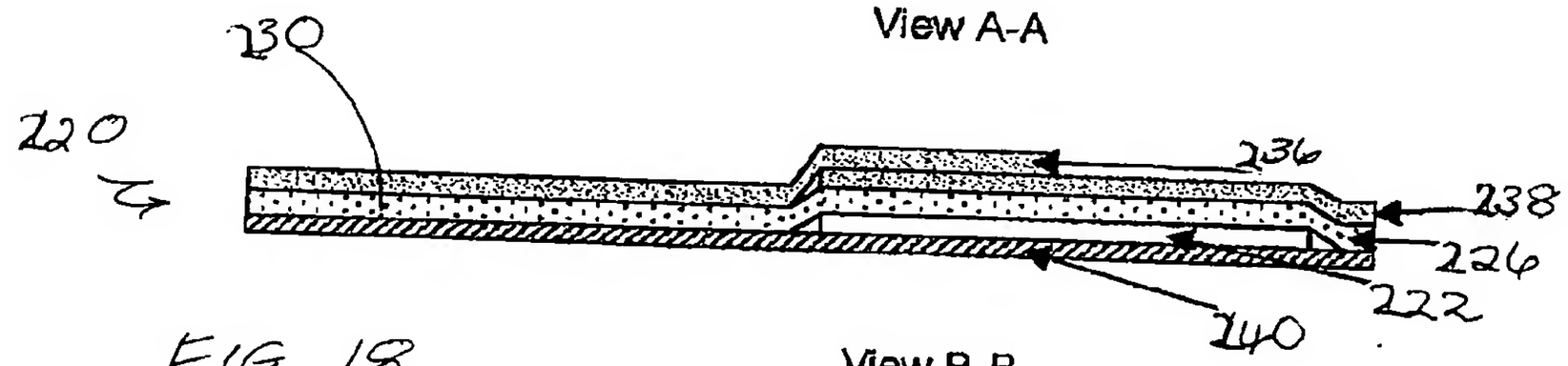


FIG. 18

View B-B

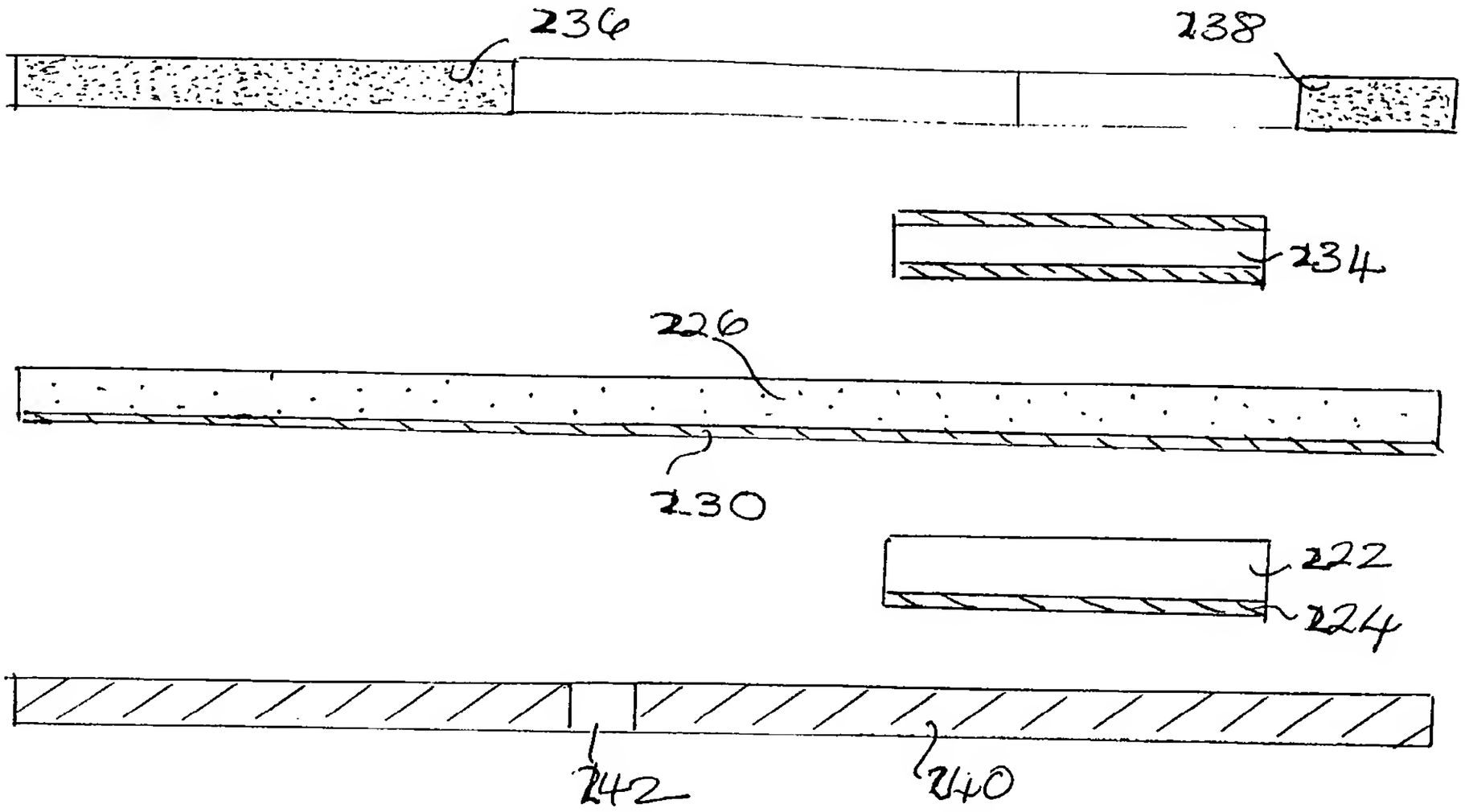
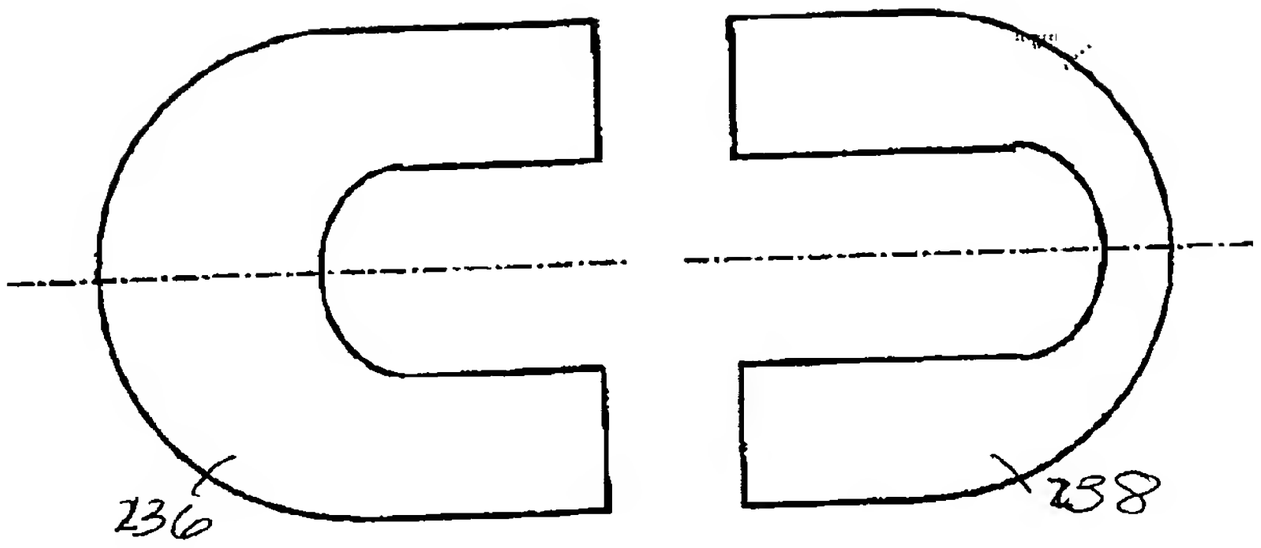
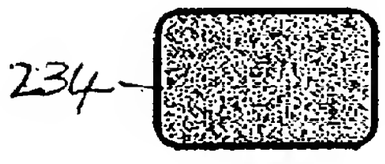
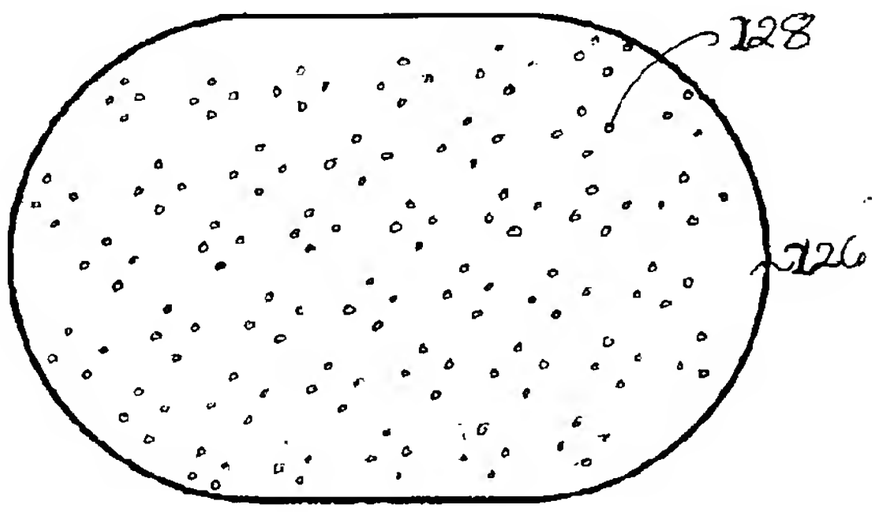


FIG. 19







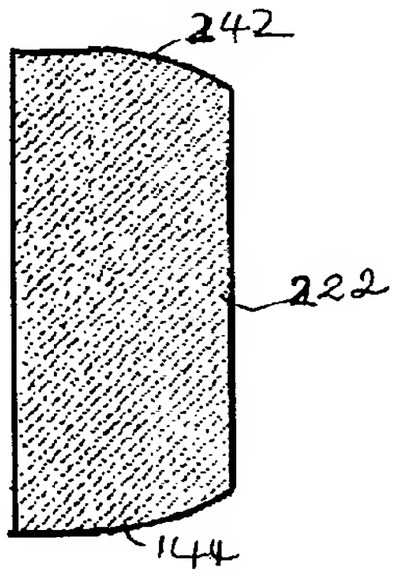
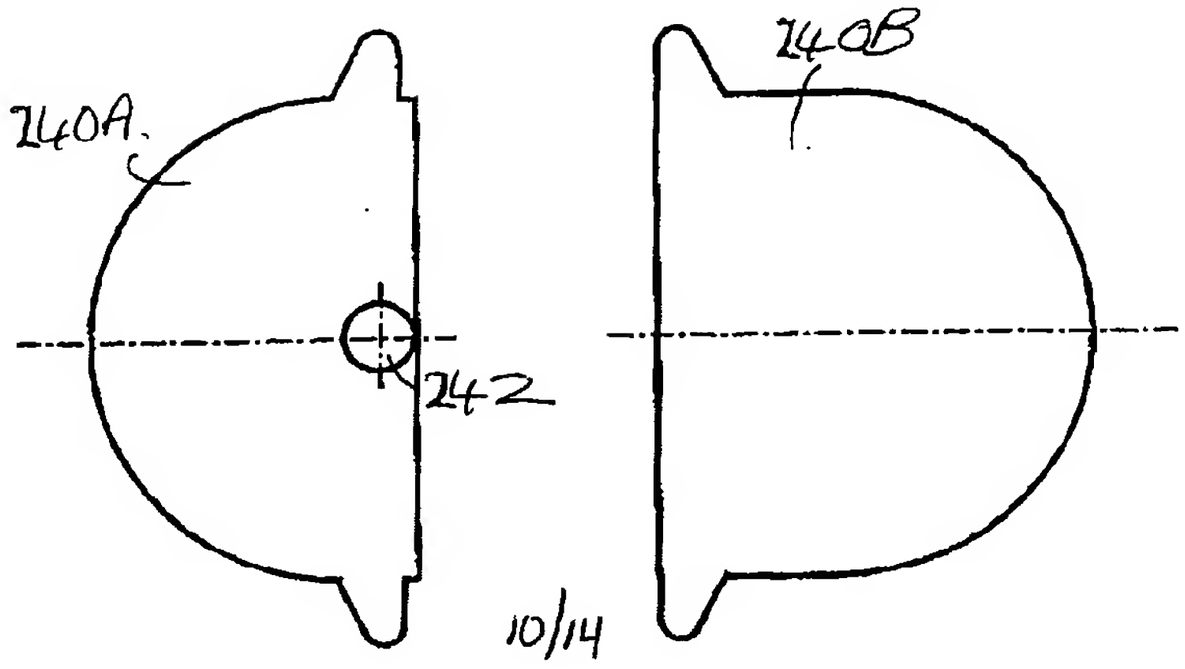


FIG. 20



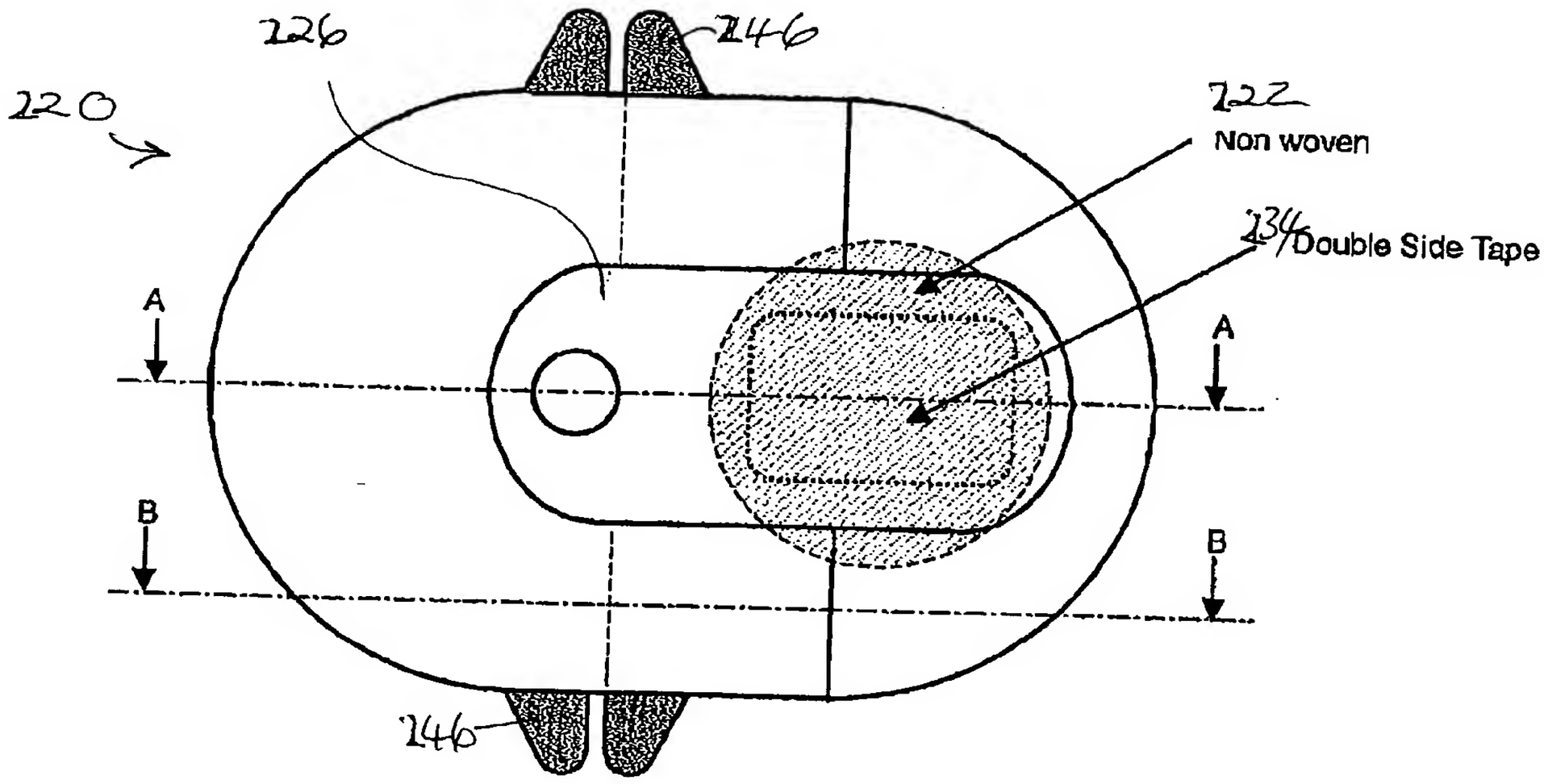


FIG. 21

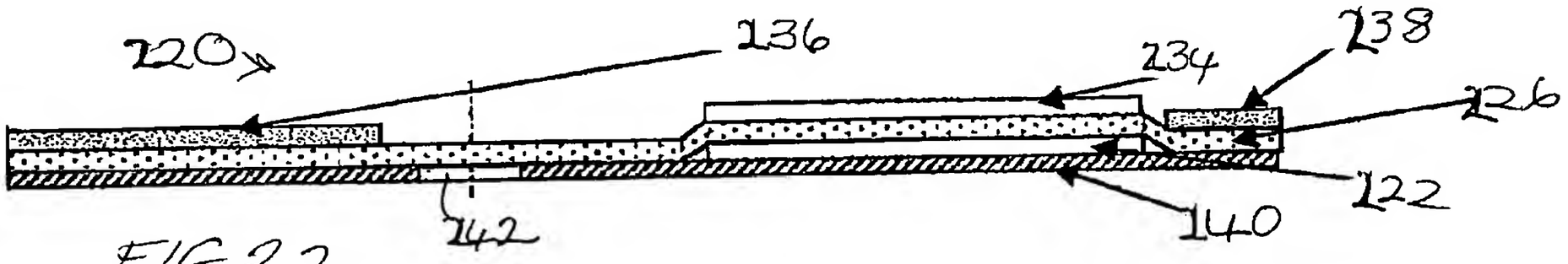


FIG. 22

View A-A

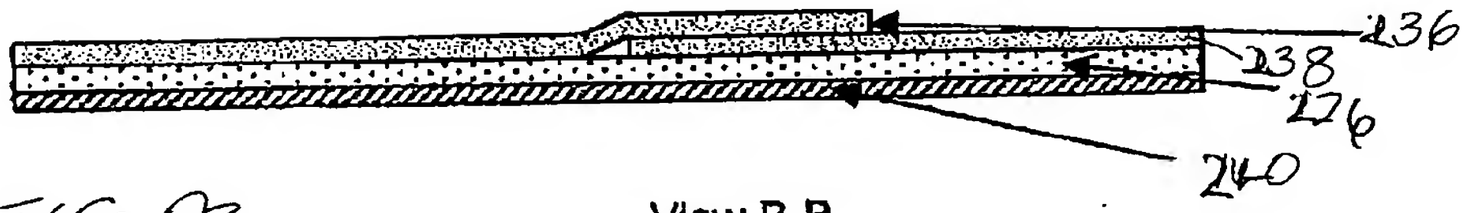


FIG. 23

View B-B

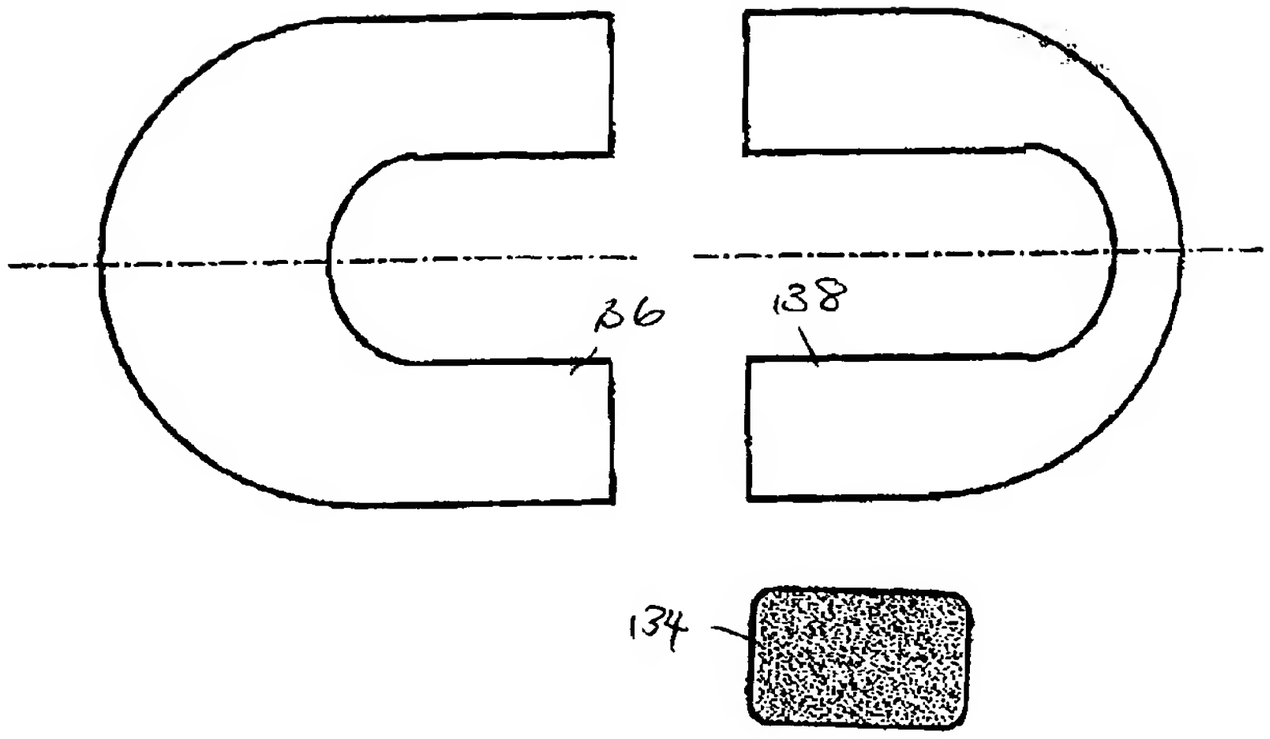
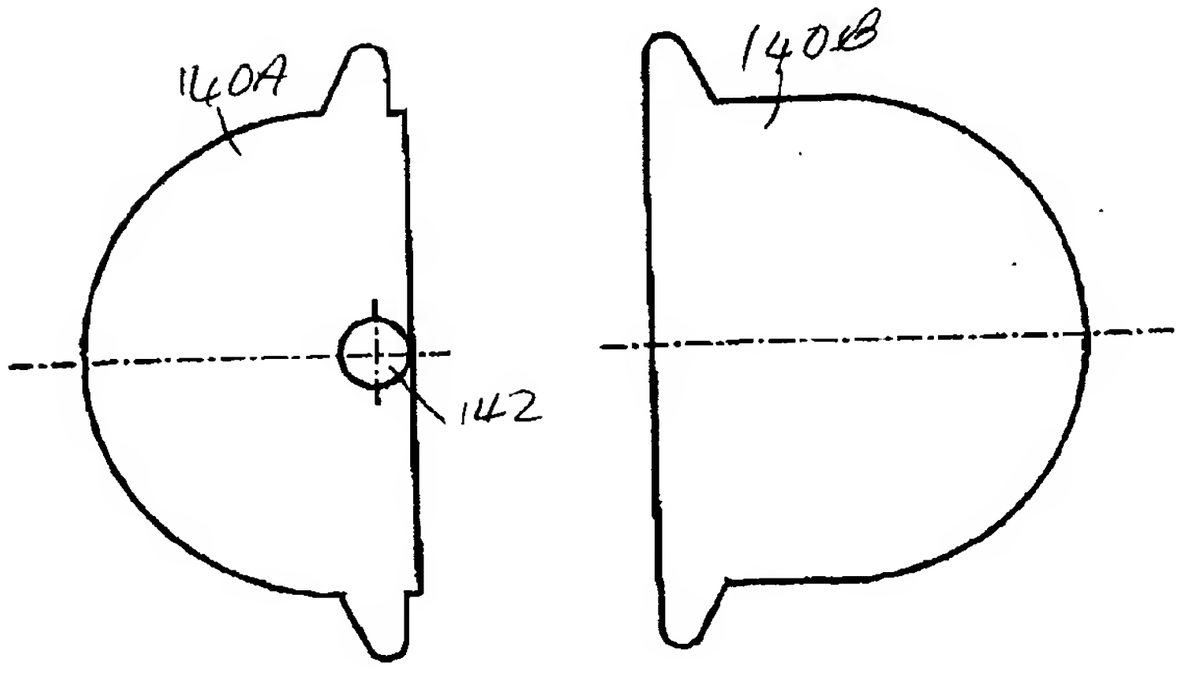


FIG. 24



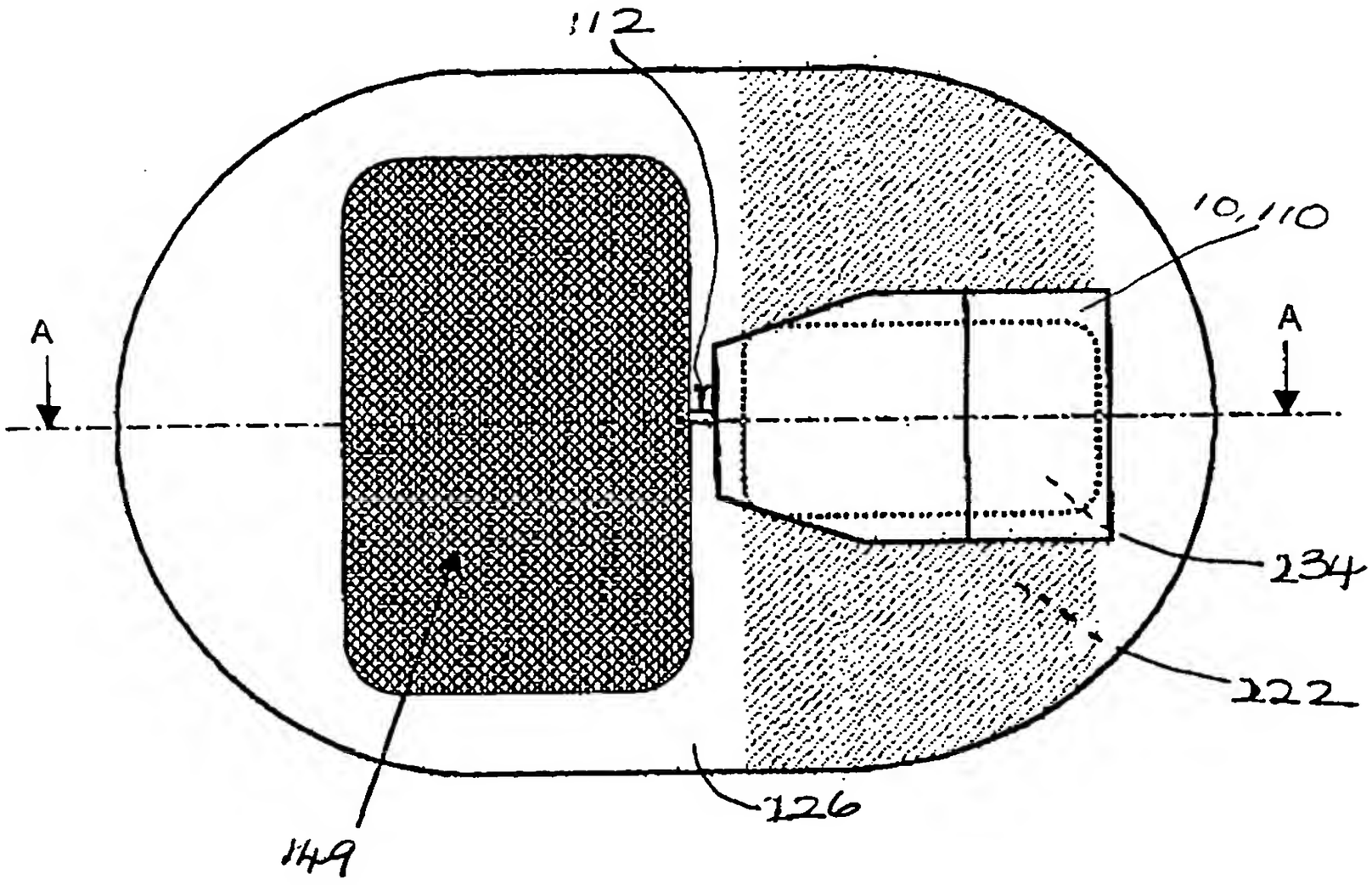

112
10,110
A
A
234
222
126
149

FIG. 25

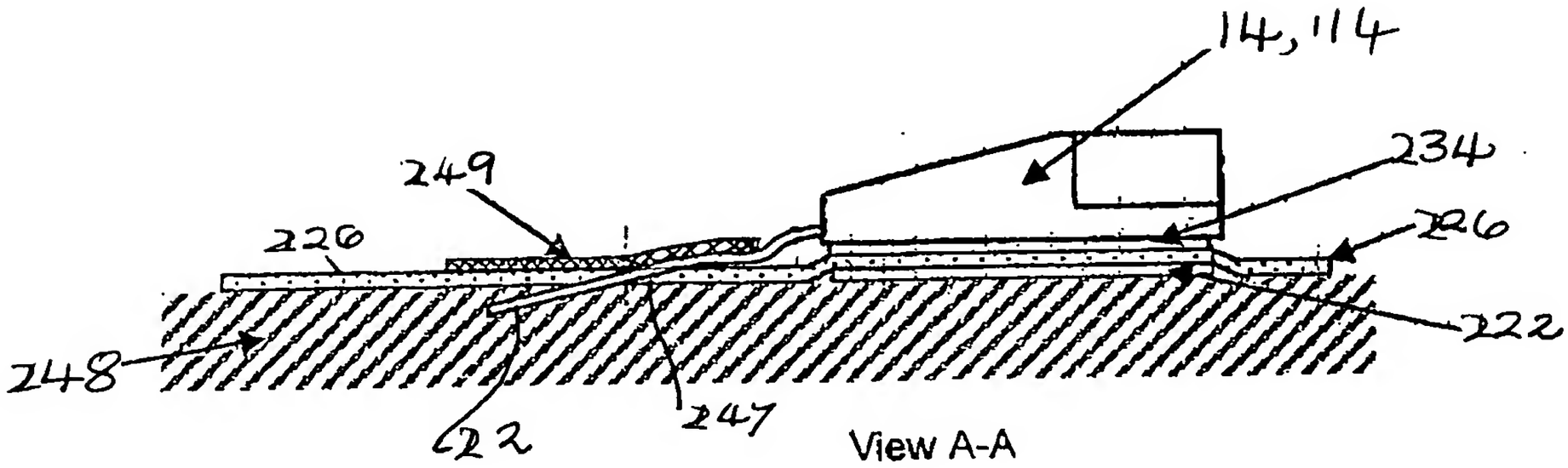

14,114
249
234
226
226
248
222
22
247
View A-A

FIG. 26

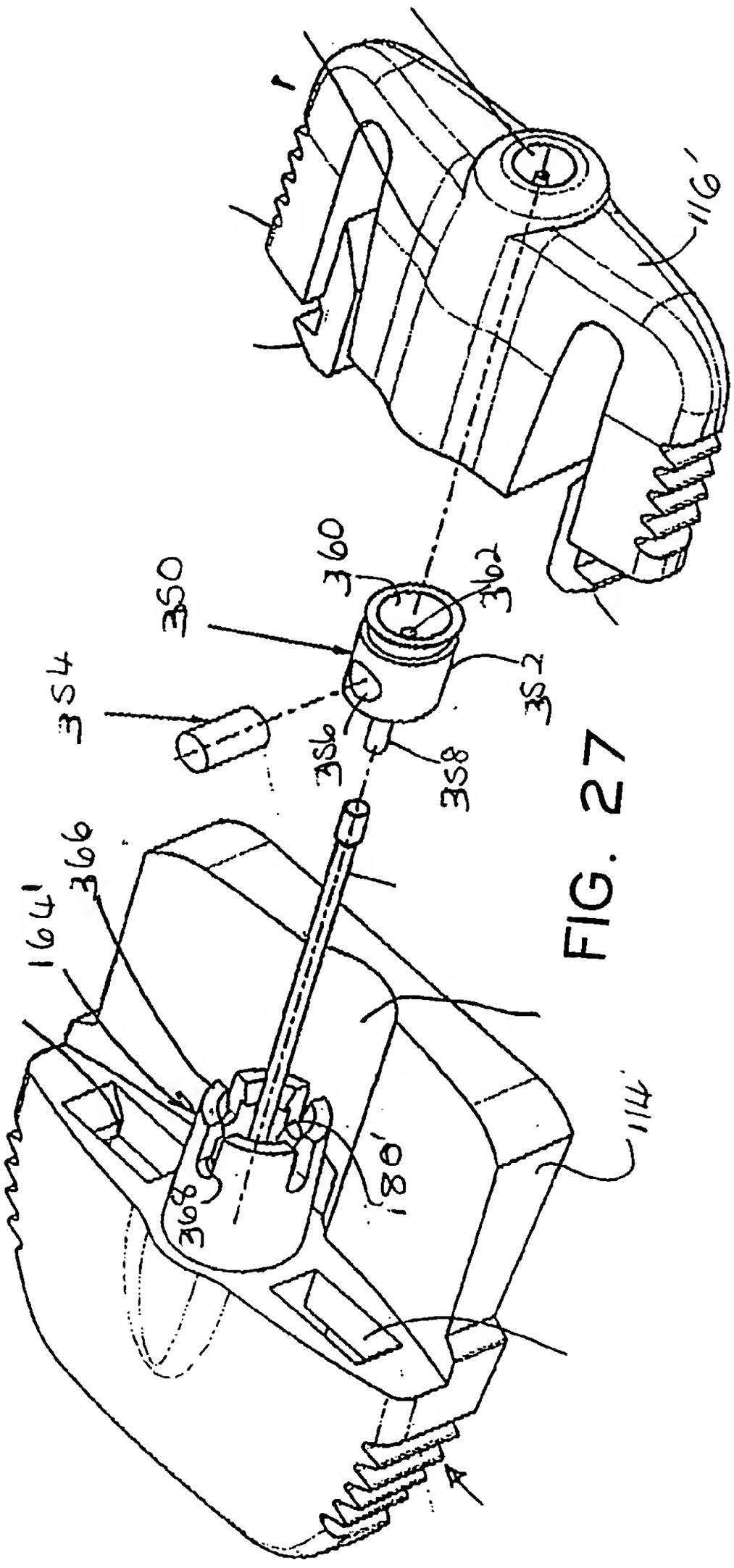

1
116'
350
360
362
354
352
356
358
366
164'
180'
368
114
A

FIG. 27

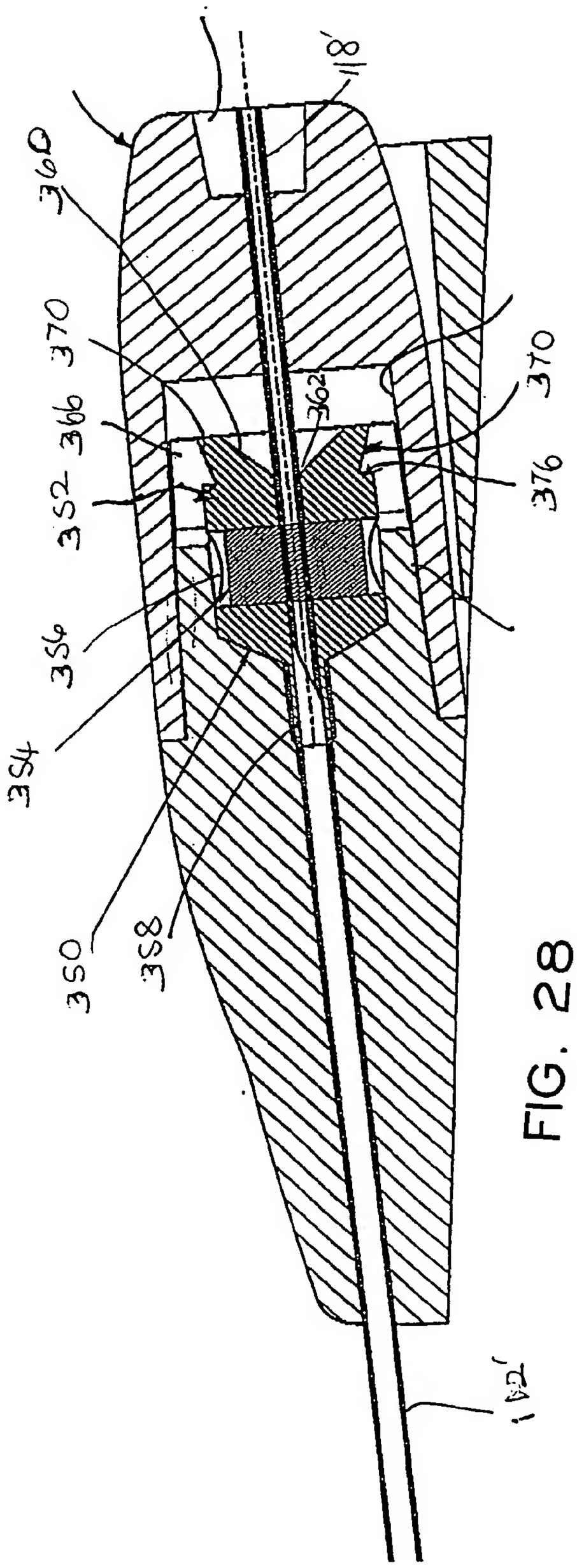

118'
360
370
366
362
352
354
356
350
358
376
182'

FIG. 28